EXHIBIT G

Exhibit G – SEALED excerpts of Plaintiffs' Expert Witness K. Keyes Transcript of Deposition (Sept. 15, 2020)

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE MARKETING OPINIONS OF DRS. ANNA LEMBKE, KATHERINE KEYES, ANDREW KOLODNY, AND JAKKI MOHR

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            IN THE UNITED STATES DISTRICT COURT
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         FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
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     THE CITY OF HUNTINGTON,
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               Plaintiff,
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                                         CIVIL ACTION
     vs.
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                                       NO. 3:17-01362
     AMERISOURCEBERGEN DRUG
     CORPORATION, et al.,
8
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               Defendants.
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     CABELL COUNTY COMMISSION,
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                Plaintiff,
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13
     vs.
                                              CIVIL ACTION
                                            NO. 3:17-01665
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     AMERISOURCEBERGEN DRUG
     CORPORATION, et al.,
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                Defendants.
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              Videotaped and videoconference deposition
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     of KATHERINE KEYES taken by the Defendants under
     the Federal Rules of Civil Procedure in the above-
20
     entitled action, pursuant to notice, before Teresa
     S. Evans, a Registered Merit Reporter, all parties
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     located remotely, on the 15th day of September,
     2020.
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PROCEEDINGS

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VIDEO OPERATOR: Good morning. We are going on the record at 8:59 a.m. on September the 15th, 2020. Please note that microphones are sensitive and may pick up whispering, private conversations and cellular interference. Please turn off all cell phones or place them away from the microphones as they can interfere with the deposition audio.

Audio and video recording will continue to take place unless all parties agree to go off the record. This is Media Unit 1 of the video recorded deposition of Katherine Keyes taken by counsel for the defendant in the matter of City of Huntington and Cabell County Commission versus AmerisourceBergen Drug Corporation, et al, filed in the United States District Court for the Southern District of West Virginia, being Civil Action Nos. 3:17-01362 and 3:17-01665.

This deposition is being conducted remotely via Zoom conferencing. My name is Adam Hager from the firm Veritext, and I'm the videographer. The court reporter is Teresa Evans from the firm Veritext.

Page 9 I'm not authorized to administer an 1 2 oath; I am not related to any party in this action; 3 nor am I financially interested in the outcome. Counsel and all present in the room and 4 5 everyone attending remotely will now state their appearances and affiliations for the record. 6 7 If there are any objections to proceeding, please state them at the time of your 8 9 appearance, beginning with the noticing attorney. This is Tim Hester, 10 MR. HESTER: 11 counsel for Defendant McKesson of the law firm of 12 Covington & Burling, and with me on the video is my 13 colleague, Stephen Petkis. 14 MR. ARBITBLIT: This is Don Arbitblit 15 with Paulina do Amaral and Britt Cibulka, Lieff Cabraser Heiman & Bernstein, for the Plaintiffs. 16 17 MS. CAMPBELL: Molly Campbell from 18 Reed Smith on behalf of AmerisourceBergen. 19 MR. METZ: Carl Metz, Williams & 20 Connolly, on behalf of Cardinal Health. 21 MS. SMITH: Christina Smith, Powell & Majestro, on behalf of the Plaintiffs. 22 If there are no 23 VIDEO OPERATOR: further appearances to be noted, would the court 24

Page 10 reporter please swear the witness. 1 2 (The witness was sworn.) 3 KATHERINE KEYES was called as a witness by the Defendant, and 4 5 having been first duly sworn, testified as follows: EXAMINATION 6 7 BY MR. HESTER: Good morning, Doctor Keyes. My name is Tim 8 9 Hester, and I'll be taking your deposition today. Since this is a Zoom deposition, let me just begin 10 by setting the stage. Where are you right now? 11 I am in the law offices of Lieff Cabraser 12 13 in New York. Is there anyone else with you in the room? 14 Ο. 15 Α. Yes. 16 0. Who else is with you in the room? 17 Paulina do Amaral. Α. 18 And do you have a box that we -- that we Q. sent to you? Is that box there somewhere in the 19 room with you? 20 21 Α. Yes. 22 And are there any other papers that you're 23 going to be consulting aside from papers that we'll 24 ask you to open up out of that box?

Page 11 Α. No. 1 2 Ο. Okay. Let me ask you, if you could, open 3 up the box and let's have you pull out Exhibit 2, please. 4 KEYES DEPOSITION EXHIBIT NO. 2 5 6 (Expert Report of Katherine Keyes, PhD 7 dated August 3, 2020 was marked for identification purposes as Keyes 8 9 Deposition Exhibit No. 2.) 10 Α. And I should open it? 11 Yes. Yes. Sorry for these mechanics --Ο. Quite all right. 12 Α. 13 -- but yes. Doctor Keyes, do you recognize Q. Exhibit 2? 14 15 Α. I do. And this is the report you submitted in 16 Ο. 17 this litigation; is that correct? 18 Α. Yes. 19 And you're stating the opinions that are 20 set forth in that report? 21 Α. I am. Are you stating any opinions in this 22 23 litigation that are not set out in the report? 24 Α. No.

- Q. And I understand that you are relying on the studies and the facts that you specifically cite in the report; is that correct?
 - A. Yes.

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- Q. Are there any other specific studies or specific facts that you are relying on to support your opinions that are not stated in the report?
- A. Not specifically. I mean, I have considered other materials since the report has been submitted, so to the extent that there are new materials on the Materials Considered list, I may use those as well.
- Q. Are you relying on any of these other materials that you've reviewed since you submitted your report to support your opinions?
- A. The materials I've considered support my opinions, and so to the extent that I have considered them since submitting the report, I -- I rely on them.
 - Q. What materials are you referring to?
- A. I believe there is a Supplemental Materials Considered List that has been submitted.
- Q. Yes, and we've seen that. So we've seen the Supplemental Materials List. Is there anything

Page 13 else aside from what's listed in those supplemental 1 2 materials that you are relying on to support your 3 opinions? Α. 4 No. 5 Ο. Could you open up Exhibit 104, please? KEYES DEPOSITION EXHIBIT NO. 104 6 7 ("Opioids - CT2 (WV) - Dr. Katherine Keyes Expert Report, Errata Sheet 8 9 (August 24, 2020) was marked for 10 identification purposes as Keyes 11 Deposition Exhibit No. 104.) 12 Α. I have something that says "Exhibit 1." 13 Yeah, Exhibit 1 is not very interesting. Ο. It's just the notice of your deposition. 14 15 probably don't need to spend time with it. Oh, Exhibit 104 as in --16 Α. 17 Ο. 104. 18 Α. Okay. 19 There's no real logic to the Q. Yeah. 20 numbering, I'll tell you that. 21 Α. Okay. Good to know. It's going to take me a minute. 22 23 MS. DO AMARAL: Mr. Hess, is Exhibit 24 104 one of the exhibits that you sent to us

Page 14 electronically last night? 1 2 MR. HESTER: Oh, sorry. Yes, it may 3 well be. It's the report errata that we received from Doctor Keyes. 5 Α. I have it. Is it in there, Doctor Keyes? 6 Q. It is. Α. Okay, great. Could you open that one up? 8 9 And these are the errata that you submitted with 10 respect to your report; is that correct? 11 Α. Yes. And just for the record, this is marked as 12 13 Exhibit 104. Are these changes, Doctor Keyes, that you discovered after you submitted your report? 14 15 Α. Yes. 16 Ο. How did you discover them? 17 MR. ARBITBLIT: Time out. Tim, I'm 18 just going to instruct the witness that she cannot 19 -- I'll instruct her not to answer about any 20 discussions with counsel which are confidential and 21 privileged. 22 Well, what I wanted to ask, Doctor Keyes, 23 Did you discover them upon your review of the 24 report? Did you see some errors that needed to be

Page 15 corrected? 1 2 Α. Yes. 3 Q. And do you have any other corrections to your report aside from those that are reflected in Exhibit 104? 5 Α. Not at this time. 6 7 Doctor Keyes, I wanted to ask what your Ο. hourly rate is for your testimony in this matter? 8 9 Α. \$550 per hour. 10 Ο. And is there any different rate that you're paid for testifying either in a deposition or at 11 trial? 12 13 That is my rate for testimony, \$550. Α. So it's your rate for all your work in the 14 Ο. 15 case? 16 No, for preparation, I charge \$400 per 17 hour. 18 And do you know -- and I take it you have testified now in the opioid litigation in Ohio and 19 in New York and now this litigation in West 20 21 Virginia. Correct? Α. 22 Yes. 23 Do you know roughly how much you've been paid in total for all of your work in these opioid 24

Page 16 litigation matters? 1 2 Α. Yes. Roughly \$175 --3 MR. ARBITBLIT: Time out. Tim, I don't want to interrupt your flow. I just want to 4 mention that there's been back and forth which I 5 don't know whether you're following the back and 6 7 forth about billing. I understand from seeing back and forth -- this is what I saw that the two sides 8 9 agreed to. Neither side produces invoices, provide hourly rate, number of hours and amount billed in 10 11 this case, not overall opioid litigation billing. 12 Is that your understanding? Or do you 13 have a different understanding? 14 MR. HESTER: I haven't really been 15 following the back and forth, Don. I -- it's just one question I wanted to ask which seems like a 16 17 legitimate question, which is: How much has Doctor 18 Keyes been paid for her work in all the opioid 19 litigation? 20 MR. ARBITBLIT: Tim, I agree that it's 21 a legitimate question. However, if it's going to be legitimate on one side, it has to be legitimate 22 on both sides, and from what I've seen -- I'm happy 23 24 to have her answer the questions that I just read

Page 17 to you that I've seen agreed and leave it for later 1 2 in the deposition if you want to consult with your 3 team and have a basis to add to what's been agreed. I don't -- I'm not trying to be an 4 5 obstructionist; I'm just trying to be the team player that follows the rules that my team and your 6 7 team seem to have agreed on. MR. HESTER: All right. 8 9 Q. Well, Doctor Keyes, how much have you been 10 paid to date for your work in this West Virginia 11 litigation? And I apologize. Just before answering --12 13 I have a technical problem, which is that I lost the realtime, so --14 15 Ο. Okay. Can you --16 Α. Yeah. I can answer while that's being pulled up. I just wanted to --17 18 Q. All right. Okay. 19 Α. So --20 Do you know how much you've been paid to Ο. 21 date for your work testifying in this West Virginia litigation? 22 23 In the West Virginia litigation? Α. 24 Q. Yes.

- A. I have been paid approximately \$60,000, I believe.
- Q. And that reflects -- is that the reflection of the hours you've worked thus far in the West Virginia litigation? In other words, the payments are up to date?
- A. I -- what do you -- by "up to date," you mean like as of yesterday or --
 - Q. Well, when you said you've been --
 - A. That's how much I've invoiced.
 - O. Excuse me?
- A. I'm sorry, that's how much I've invoiced.
 - Q. Okay. All right. Thank you.
- I -- do you have any stake in the outcome of the litigation? In other words, do you receive any bonus or extra payment depending on the outcome?
- 18 A. No.

Q. Let me ask you, Doctor Keyes, just a few background questions so we have a common understanding here. You understand that the defendants in this West Virginia litigation are distributors of controlled substances, including prescription opioids, right?

A. Yes.

- Q. And they're licensed by the federal and state government to distribute those opioids; is that right?
 - A. Yes.
- Q. And do you also understand that these distributors distribute a wide range of other medical products in addition to prescription opioids?
- A. Yes.
 - Q. Do you understand that these distributors buy prescription opioids from drug manufacturers and then sell them to pharmacies?
 - A. Yes.
 - Q. And you understand that the pharmacies then dispense prescription opioids to patients based on prescriptions written by doctors; is that right?
 - A. That's right.
 - Q. And do you have any knowledge of the customers served by these three distributors?
 - A. I have general knowledge about kind of different pharmacy chains and different pharmacies that would be served by the distributors. But it's not my specific area of expertise.

- Q. So your general knowledge is that they -- is that they deal with pharmacies, both chains and smaller pharmacies?
 - A. That's my general knowledge, yes.
- Q. Do you have any knowledge of their market shares?
 - A. I don't.
- Q. Do you have any knowledge in relation to their operations specifically in Cabell County and Huntington?
 - A. No.

- Q. And I take it that your opinions are not dependent on knowledge of these distributors' operations in Cabell and Huntington. That's not something that you studied for purposes of your opinions?
- A. The -- I have opinions that include the distribution of opioids in Cabell County. So to the extent that the distributors distributed in Cabell County, that is included in my opinions.
- Q. But you haven't undertaken to develop any knowledge about their operations in Cabell County for purposes of providing your opinions, correct?

 MR. ARBITBLIT: Objection.

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Page 21 I -- perhaps you could clarify what you mean by "operations." Q. Well, you didn't -- you didn't study what -- what their market shares or distribution patterns are in Cabell and Huntington, did you? I studied the distribution patterns of opioid distribution in Cabell. I did not study market shares. Q. What did you study about distribution patterns? The amount of opioids that are distributed in the counties. In the aggregate by these three distributors and others? That's what you were looking at, is the aggregate distribution? That's -- that's correct. Α. Let me ask you to pull out Exhibit 18, Ο. please.

KEYES DEPOSITION EXHIBIT NO. 18

("Rates of opioid misuse, abuse, and

addiction in chronic pain: A

systematic review and data synthesis"

by Vowles, et al. dated April 2015 was

marked for identification purposes as

Keyes Deposition Exhibit No. 18.)

Q. And for the record, Exhibit 18 is a document written by Kevin Vowles and others entitled "Rates of opioid misuse, abuse and addiction in chronic pain: a systematic review and data synthesis."

Doctor Keyes, I take it you're familiar with this document?

A. I am.

- Q. And you cite -- you cite this report, or this document, in your report. Is that correct?
 - A. Yes.
- Q. Well, let me ask you if you could turn to your report. I think if we go to page 17 of your report, Exhibit 2.

MR. ARBITBLIT: Counsel, before you ask your next question, I just want to interpose an objection based on Rule 26 that this deposition should not be duplicative of past depositions, and in particular, the Court must limit the frequency or extent of discovery otherwise allowed by these rules if it determines that the discovery sought is unreasonably cumulative or duplicative, and the Vowles study has been the subject of prior

Page 23 questioning and opportunity to question thoroughly 1 2 at previous depositions of this witness. 3 I will allow the question, but we'll see where it goes, and if it is going to be redundant or duplicative, then I will object and 5 we'll have to address that. 6 7 MR. HESTER: Well, we don't need to spend time on that right now. I mean, I would just 8 9 say that she's -- Doctor Keyes has submitted a new 10 report in the -- in the West Virginia litigation, 11 and I'm asking her about the contents of her report as submitted in West Virginia. 12 13 So I think --MR. ARBITBLIT: I understand that. 14 15 understand that. 16 MR. HESTER: I think it's fair play. 17 But I'm not going to -- I'm not going back over --18 my plan is not to go back over ground that's been covered before. My plan is to focus on questions 19 that relate to the expert report Doctor Keyes 20 21 submitted in this case. MR. ARBITBLIT: I understand that's 22 23 the plan, and I appreciate your position. I would just say that the Vowles article does not deal 24

Page 24 specifically with West Virginia, and to the extent 1 2 that it has been the subject of prior discussion, 3 if you have something new to ask about it that hasn't been covered or the opportunity for it 5 hasn't been covered, that would not be duplicative. MR. HESTER: Well, you are right --6 7 you are right that you're interfering with the deposition. 8 9 Let's keep going, and we'll come back 10 to it if we need to. 11 MR. ARBITBLIT: I did not say that I am interfering with the deposition, Counselor, and 12 13 I am not. So you are. Let's --14 MR. HESTER: 15 let's keep going. I understand your position. 16 Let's keep going. BY MR. HESTER: 17 Doctor Keyes, you cite the Vowles study at 18 page 17 of your report. That's the basis for this 19 chart that you submitted; is that correct? 20 That's correct. 21 Α. 22 Ο. And --23 I'm sorry, can I correct that? I'm sorry. Α. 24 Can you repeat the question?

- Q. Yes. Is the -- is the chart at Exhibit 17 of your report, that's the source for the -- the Vowles study is the source for that chart.
- 4 | Correct?

- A. It is one source. I've also corroborated the numbers in Figure 1 with other sources as well.
- Q. But the numbers you cite in that chart are from the Vowles study?
- A. That's one study that has this range of numbers.
- Q. But the numbers you pulled out are taken out of the document -- out of the Vowles document; is that right?
- A. That's correct. I just want to -- to amend my -- the answer to acknowledge that it's not just the one study that reports this range of numbers.
- Q. And -- and your reliance on Vowles is based on your review of the literature; is that correct?
 - A. Yes.
- Q. And you have not undertaken any studies yourself. You reviewed other studies in the literature to decide that you would rely on Vowles. Is that right?
 - A. I have -- I have undertaken studies of

Page 26 opioid use disorder myself. So --1 2 But for purposes of what you've set out in 3 your report here, it's based on a review of literature. Is that right? At pages 16 and 17 of the report, it's based on a review of literature? 5 Yes. Page 16 and 17 is based on a review 6 7 of the literature. And am I right that the Vowles paper is 8 9 focused solely on chronic noncancer pain treatment? The inclusion criteria for studies in the 10 -- in the Vowles review is chronic pain. So --11 And --12 Q. -- it could have other conditions as well, 1.3 but the focus is chronic pain. 14 15 Right. So patients who are taking opioids 16 for chronic pain, noncancer chronic pain, that was 17 the inclusion criteria for the Vowles study? 18 Α. That's correct. 19 And are you aware that there are other uses for opioids, other medical uses, for opioids aside 20 21 from chronic noncancer pain? Yes, I am. 22 Α. 23 And I take it that prescription opioids Ο. 24 have a legitimate medical use for the treatment of

Page 27 acute pain and acute injury. Do you agree with 1 2 that? 3 MR. ARBITBLIT: Objection. I wouldn't make a blanket statement about 4 Α. 5 the legitimate medical use of opioids, no. Do you have knowledge about the legitimate 6 medical use of opioids? 7 Α. Yes. 8 9 And what's your knowledge about the legitimate medical use of opioids? 10 11 I rely on -- the literature that I cite in this report indicates that, in general, the use of 12 opioids for pain relief is -- should be limited and 13 -- to, you know, certain conditions. I don't think 14 15 "legitimate use" is a blanket term that I would 16 use. 17 Do you have any knowledge of the legitimate Ο. 18 medical uses for opioids? Do you have knowledge of 19 that? 20 MR. ARBITBLIT: Objection. 21 Α. Yes. And what's -- and -- what -- can you 22 23 describe for me a legitimate medical use of a 24 prescription opioid?

Page 28 MR. ARBITBLIT: Objection. 1 2 Not as a -- not as a blanket statement, no. Α. 3 Ο. Let me ask you to --It's a case-by-case basis. 4 Α. 5 Let me ask you to look at Exhibit 106, Ο. please. 6 7 MR. ARBITBLIT: Are those the supplement --8 9 MR. HESTER: Those may be the ones we 10 sent overnight. Sorry. 11 Doctor Keyes, let me ask you -- on the ones Ο. 12 we --13 MR. HESTER: We sent several studies that we were going to use today -- or documents 14 15 that we were going to use today by e-mail. Did you have a chance to print those out or -- ? 16 MS. DO AMARAL: We did -- we did have 17 18 a chance -- I'm sorry. 19 MR. HESTER: Sorry, Paulina, there's 20 feedback. 21 MS. DO AMARAL: We did have a chance to print them out. We haven't had a chance to 22 collate them. We had some difficulties with the 23 24 connection this morning, but I have them here.

Page 29 will take just a moment to get my hand on that. 1 2 MR. HESTER: Okay. And what I wanted 3 to show to Doctor Keyes is Exhibit 106. BY MR. HESTER: While we're doing that, just one more 5 threshold question, Doctor Keyes: I take it that 6 Vowles itself is a review of other studies in the 7 literature; is that right? 8 Α. 9 That's correct. 10 MS. DO AMARAL: Counsel, we need a 11 couple minutes. It might make sense to move --MR. HESTER: Okay, all right, so it 12 13 will take you a little bit. I'll circle back to 14 that. 15 Doctor Keyes, we spoke a minute ago about 16 the fact that the Vowles study is focused on 17 chronic use of opioids; is that right? 18 I think there is information on the range of duration. I don't mean to hesitate; it's just I 19 don't know that -- I don't know -- I quess, what do 20 21 you mean by "chronic use"? Well, we spoke before that the criteria for 22 23 inclusion of studies in this survey was treatment 24 of chronic noncancer pain. Correct?

A. That's correct.

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- Q. And I just wanted to ask you then: What's your understanding of the word "chronic"?
- A. I'm trying to see what -- I don't believe that there's a definition in terms of -- aah.
- "Persistent pain lasting longer than three months" is the definition that's used in this.
 - Q. And the --
- A. The inclusion criteria did not include that the opioids were used for longer than three months, for example.
- Q. That was my question, whether this -- the inclusion criteria were people with chronic pain or people who used opioids chronically?
- A. In terms of the inclusion criteria, I think the focus was on people with chronic pain.
- Q. Do -- let me ask you to look at page 16 of your report, please. Do you have it there?
 - A. Yes.
- Q. And in the middle of the full paragraph on that page, there's a sentence almost exactly halfway through. It says, "Individuals in the study had been using opioids for an average of 5" to "six years."

Page 31 Do you see that? 1 2 Just give me a moment. Α. 3 Q. It's about halfway through your paragraph. So that's referring to the Jamison, et al 4 Α. 5 study, 2010. Ο. Oh, that's a reference to Jamison, et al; 6 7 it's not a reference to Vowles? Α. That's correct. 8 9 Q. Do you know -- do you know the average use 10 of use -- sorry. 11 MR. HESTER: Let me strike that. 12 Q. Do you know the average period of use in 13 the studies that are covered by the Vowles study? No, not -- not off the top of my head. 14 Α. 15 Ο. Do you --16 Α. Sorry. 17 I take it also -- let me ask you about Ο. dosing levels. You're familiar with this concept 18 of dosing levels; is that correct? 19 20 Α. I am. 21 And dosing levels refers to the -- to the 22 level of dose of a prescription opioid that the 23 patient is taking, correct? 24 Α. Yes.

- Q. And there's no reference in Vowles to dosing levels, is there?
- A. There is in the underlying studies that are part of Vowles. But in terms of what Vowles, et al report, I do not believe that there is reference to the dosing levels in the underlying studies.
- Q. And in the chart at page 17 of your report, there's no reference to dosing levels, correct?
 - A. In Figure 1?
- 10 Q. Yes.

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- A. There's no dose information in Figure 1.
- Q. And let me ask you to look at page 19 of your report, please.

And again, I -- I'll point you about halfway through the bottom paragraph on the page. There's a sentence that reads in your report, "It is well-documented that risks of opioid-related adverse outcomes are heterogeneous by dose and duration of use."

Do you see that?

- A. I do.
- Q. What do you mean by the risks of "adverse outcomes are heterogeneous by dose and duration of use"?

Page 33

- A. Typically that means that adverse outcomes increase with an increase in dose and duration.

 There's a dose response relationship between harm and opioid use.
- Q. And so when you say "heterogenous" in that setting, you mean that the risks are going to be different depending on the level of the dose, as well as the duration. Right?
- A. They're going to increase with dose and duration, yes.
- Q. Well, they'll be different with different doses and different duration, correct?

MR. ARBITBLIT: Objection.

- Q. Now, Vowles is only measuring the percentage of chronic noncancer pain patients who engage in misuse of prescription opioids, right?

 MR. ARBITBLIT: Objection.
- A. Sorry, I'm just waiting for the realtime so I can read this.

MS. DO AMARAL: Counsel --

- A. Vowles is measuring the percentage of misuse, abuse and addiction identified in these 38 studies.
 - Q. And so misuse is using prescription opioids

Page 34 without a prescription or not as directed by a 1 2 doctor; is that correct? 3 MR. ARBITBLIT: Objection. Asked and answered at length in the New York deposition. 4 5 You can go ahead. Ο. That is included in the definition of 6 7 "misuse," but the underlying studies that have measured misuse in the Vowles study have a more 8 9 inclusive definition that includes other symptoms 10 of opioid use disorder. 11 So the -- Vowles also reports a figure for addiction which you reflect in your chart on page 12 13 17 of opioid use disorder from moderate to severe of 8 to 12 percent. Correct? 14 15 Α. Yes. 16 Ο. And that's an 8 to 12 percent that flows out of the misuse of prescription opioids, right? 17 18 Α. I'm not sure I understand what that means. Well, the 8 to 12 percent is a subset of 19 people who are misusing the prescription opioids, 20 21 correct? 22 MR. ARBITBLIT: Objection. 23 It's people who meet criteria for opioid

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use disorder at that level. I guess I'm not -- I'm

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not quite sure what you mean by "subset."

- Q. Well, what I meant is that the way you've drawn your Venn diagram here on page 17, there's an opioid use disorder from moderate to severe of 8 to 12 percent. Those are people who are engaged in misuse of opioids. Is that right?
 - A. Generally speaking, yes.
- Q. Now, these two figures the 22 to 29 percent figure in the Vowles report that you show on Figure 1 and the 8 to 12 percent figure those are both measuring prevalence and not incidences; is that correct?
 - A. That is correct.
- Q. And that would mean it could include people who had either moderate or severe opioid use disorder before they began taking prescription opioids. Is that right?
- A. I mean, to get moderate to severe opioid use disorder, you have to be exposed to opioids.
- Q. But not necessarily pursuant to a doctor's prescription. Is that right?
- A. There is generally a substantial overlap between nonmedical and medical use, although it's not -- I mean, I would agree with you that in terms

Page 36 of the prevalent case, we don't know the entire 1 2 history of prescription opioid use. 3 Q. And so I'm -- I think this is a point that we can probably readily agree on, that when you're 5 looking at, let's say, this 22 to 29 percent figure of misuse, that's going to include people who are 6 7 engaged in misuse of prescription opioids before they received a prescription from a doctor. 8 9 MR. ARBITBLIT: Objection. Assumes facts not in evidence. 10 11 Yeah, I don't have any knowledge of that. 12 I mean --Q. Well --1.3 -- that's --14 15 -- prevalence -- prevalence captures a point that people have a certain characteristic at 16 17 a certain point in time in a study. Is that right? 18 Α. It can. Well, when you -- when you distinguish 19 between prevalence and incidence in your prior 20 21 answer, prevalence is measuring the attributes of 22 opioid disuse -- opioid use disorder in a 23 population, correct? 24 MR. ARBITBLIT: Objection.

- A. Prevalence is measuring opioid use disorder in a population, correct.
- Q. And so that could include people who had an opioid use disorder before they took a doctor's prescription for opioids, correct?
 - A. It could.

- Q. And likely does, correct?

 MR. ARBITBLIT: Objection.
- A. I don't have any information on how likely it is.
 - Q. Okay. This is not measuring the incidence of opioid use disorder among patients who followed doctor's directions in taking prescription opioids, correct?

MR. ARBITBLIT: Objection.

- A. Those incident cases would likely be included in this assessment. It's not exclusive to that number. That's another number that we would use for public health.
- Q. But it does -- but this study, this Vowles study, is not -- is not identifying the percentage of opioid use disorder among patients who followed a doctor's prescription, correct?
 - A. It is identifying the percentage of opioid

Page 38 use disorder among patients using a doctor's 1 2 prescription. It doesn't provide information on how closely it was followed. 3 No, but it does -- it's capturing the 4 5 incidence of opioid use disorder among those who are engaged in misuse of opioids, correct? 6 7 MR. ARBITBLIT: Objection, asked and answered. 8 9 Α. So it's prevalence of opioid use disorder, 10 and it's among those with noncancer chronic pain. 11 But it doesn't get -- Vowles does not give 0. 12 us a percentage of misuse or addiction arising among patients who followed doctors' prescriptions. 13 MR. ARBITBLIT: Objection, asked and 14 15 answered. I would say that the study includes people 16 17 who are -- we don't have any information on whether 18 they're following a doctor's prescriptions or not. So that's included in the --19 Well, we know -- we know that the patients 20 21 that -- the 21 to 29 percent are people who are 22 engaged in misuse, correct? 23 People who have symptoms of opioid use

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disorder.

Page 39 And have engaged in misuse, correct? 1 0. 2 MR. ARBITBLIT: Objection. 3 Α. Generally speaking, yes. And let me ask you to look at Exhibit 98, 4 Q. 5 please. MS. DO AMARAL: Counsel, we have 6 7 Exhibit 106 when you need it. MR. HESTER: Oh, thank you. 8 I'11 9 circle back to that in a minute. MS. DO AMARAL: I will need to take a 10 11 break to get 105, however. 12 MR. HESTER: Okay. 13 KEYES DEPOSITION EXHIBIT NO. 98 14 ("The Prescription Opioid and Heroin 15 Crisis: A Public Health Approach to an Epidemic of Addition" by Kolodny, et 16 17 al. dated 1-12-15 was marked for 18 identification purposes as Keyes 19 Deposition Exhibit No. 98.) 20 98, yes? Α. 21 Q. Yes, thank you. You have that one there, 22 Doctor Keyes? 23 Α. I do. 24 Q. And for the record, Exhibit 98 is a paper

Page 40 written by Andrew Kolodny and others entitled "The 1 2 Prescription Opioid and Heroin Crisis: A Public 3 health Approach to an Epidemic of Addiction." Doctor Keyes, have you seen this 4 document before? 5 Α. I have. 6 7 And let me ask you to look at page 566, And it -- at the very top of the page -8 9 it's the first sentence of text - it says, "The incidence of iatrogenic opioid addiction in 10 patients treated with long-term OPRs is unknown 11 12 because adequately-designed prospective studies have not been conducted." 13 Do you see that? 14 15 Α. I do. 16 Ο. And do you agree with that? 17 I think there have been studies published Α. 18 that speak to this percentage that I've cited in my It's possible they were published since 19 2015. You know, this article is five years old. 20 21 I want to ask you specifically, though, not 22 about the numbers stated in your report. 23 asking about the "incidence of iatrogenic opioid

addiction in patients treated with long-term OPRs."

Page 41 Are you aware of any study that 1 2 measures the incidence of iatrogenic opioid 3 addiction in patients treated with long-term OPRs? Α. Yes, they're cited in my report. 4 5 Ο. Which study? I believe the Edlund study speaks to that, 6 Α. 7 in the claims data. Ο. Any others? 8 9 Α. I believe there are other studies that 10 measure incidence in the report. I could go through them more carefully, but there's a number 11 12 of reviews that are cited that speak to incidence. 13 The Edlund study is the one that you have Q. in mind? 14 15 I have -- yeah, I'm thinking about the 16 Edlund study, but I believe there are others as well. 17 18 When you say --Ο. 19 -- for example --20 Well, when we say "the incidence of Ο. 21 iatrogenic opioid addiction, " that means -iatrogenic opioid addiction means opioid addiction 22 arising out of -- out of treatment under a doctor's 23

care and pursuant to a doctor's prescriptions?

Page 42 Yes. 1 Α. 2 Ο. Let me ask you now to go back to Exhibit 3 That's the one we tried to get a minute ago. KEYES DEPOSITION EXHIBIT NO. 106 4 5 ("Understanding the Rural-Urban Differences in Nonmedical Prescription 6 7 Opioid Use and Abuse in the United States" by Keyes, et al. dated 8 9 February 2014 was marked for 10 identification purposes as Keyes 11 Deposition Exhibit No. 106.) Do you have it there, Doctor Keyes? 12 Q. 13 Α. T do. And Exhibit 106, for the record, is a paper 14 15 written by Doctor Keyes and others entitled "Understanding the Rural-Urban Differences in 16 17 Nonmedical Prescription Opioid Use and Abuse in the United States." 18 19 I take it you're well familiar with 20 this document? 21 Α. Yes. 22 Let me ask you to look at page E-54, And on the left hand column under the 23 24 heading for Self Medicating for Pain, there's a

Page 43 sentence that reads, "When used as prescribed under 1 2 medical supervision, opioid analgesics are 3 effective and used as standard practice in managing acute and chronic pain." 5 Do you see that? MR. ARBITBLIT: Objection. We're 6 7 going over old ground. This is the second article that's going over old ground that's been asked and 8 9 answered at length in the New York deposition. On the third strike, Counselor, I'm 10 going to get in touch with Judge Wilkes, and we'll 11 12 see if he thinks this is proper or not. 13 Q. This is a study --MR. HESTER: It would be quite ironic 14 15 to take the position asking Doctor Keyes about a study involving rural populations is not something 16 17 we can ask about. But I understand. I mean, you 18 19 MR. ARBITBLIT: It's not about ironic, Counselor; it's about duplicative. The article's 20 21 been the subject of prior questioning. Rule 26 says duplicative depositions are harassment and not 22 allowed. 23 MR. HESTER: So --24

Page 44 MR. ARBITBLIT: I do -- you can 1 2 disagree, and we do disagree. This is the second 3 I'm allowing it. I'm not going to allow it a third time. 5 MR. HESTER: We can -- we can argue --I don't want to take time arguing about it. I 6 7 would just say when an expert report is submitted in a case, I'm not sure that the concepts you're 8 9 relying on apply. But let's go ahead. 10 BY MR. HESTER: 11 12 Doctor Keyes, do you stand by that 13 sentence? I think that sentence reflected the same, 14 15 you know, deceptive information that the 16 pharmaceutical companies and distributors released. 17 Ο. So you don't stand by that sentence? 18 I think if I were to write that sentence today, I would provide a lot more nuance to that 19 20 sentence. 21 What did you mean when you wrote "opioid analgesics are effective"? 22 23 MR. ARBITBLIT: Objection. 24 It was not the topic of the paper, the Α.

Page 45 efficacy of opioid analgesics, and I think that, 1 2 again, were I to write that sentence today, I would 3 qualify that statement more. But what I meant by that at the time 4 was that there are some indications for which 5 opioids control pain. 6 7 And you just don't know what those indications are? 8 9 MR. ARBITBLIT: Object to form. I do know the -- I know what the 10 11 indications are. 12 Ο. And what are those? I don't want to make a blanket statement 13 Α. about the appropriateness of opioids. It would 14 15 have to be handled on a case-by-case basis. Oh, I just -- but when you said they --16 Ο. they control pain for certain indications, what 17 18 indications did you have in mind? 19 MR. ARBITBLIT: Objection. 20 Again, I don't want to make a blanket Α. 21 statement about all -- all uses of opioids. would be on a case-by-case basis. 22 23 Let's go back to -- let's go back to your Ο.

report, Exhibit 2, and page 17 again. So Doctor

Page 46 Keyes, looking at this Figure 1, does it reflect 1 2 that, from among these patients treated for chronic 3 noncancer pain with opioids, there were in the range of 80 -- 70 to 80 percent who did not develop 5 an opioid use disorder? I just -- let me read this. 70 to 80 6 7 percent do not have a prevalent opioid use disorder, just to be clear about the language. 8 9 And when you say "prevalent," you mean it's not -- you're distinguishing that from incidence. 10 So it would include incidence but it would be 11 broader than incidence. 12 13 MR. ARBITBLIT: Objection. I wouldn't conflate those two in that way. 14 15 Incidence is not subsumed in prevalence in that way. They're two different measures. Incidence in 16 17 this case is --What did you mean -- I didn't mean to 18 interrupt. I'm sorry. What did you mean by 19 "prevalence," that you're saying that this is 20 21 "reflecting prevalence"? 22 MR. ARBITBLIT: Objection. 23 It means that the study design was that

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opioid use disorder was assessed among people with

chronic noncancer pain, an overall percentage was estimated.

- Q. And we don't know how long they were taking the opioids for their chronic noncancer pain?

 MR. ARBITBLIT: Objection.
- A. I believe that information is in the underlying studies, so we could go to the underlying studies if that would be helpful.
- Q. How would -- is that the way you would figure out the duration of treatment for chronic noncancer pain patients in the Vowles study? You'd go and look at the underlying studies to figure out the periods of time that people were being treated with opioids?
- A. I think that would be one way to estimate duration.
- Q. Is there any other way you could think of? You don't see it in the body of the Vowles report?
- A. I don't see it in the body of the Vowles report.
- Q. And we also don't know the dosing levels for these patients being treated with chronic noncancer pain, correct?
 - MR. ARBITBLIT: Objection, asked and

Page 48 answered. 1 Α. I believe that information is in the 3 underlying studies. And again, you'd have to go back then to 4 5 look at the underlying studies to figure out what the dosing levels were? 6 Α. Yes. You mentioned -- let's turn to Exhibit 10, 8 9 please. KEYES DEPOSITION EXHIBIT NO. 10 10 11 ("The Role of Opioid Prescription in 12 Incident Opioid Abuse and Dependence 13 Among Individuals With Chronic 14 Noncancer Pain" by Edlund, et al. 15 dated July 2014 was marked for 16 identification purposes as Keyes 17 Deposition Exhibit No. 10.) 18 For the record, Exhibit 10 is a paper 19 written by Mark Edlund and others entitled "The 20 Role of Opioid Prescription in Incident of Opioid 21 Abuse and Dependence Among Individuals with Chronic 22 Noncancer Pain." 23 Doctor Keyes, you've seen this document 2.4 before?

Page 49 Α. Yes. 1 2 MR. ARBITBLIT: Objection. Counselor, 3 this was addressed at the New York deposition at page 310. Do you have any new questions about it? 4 Or are we replowing old ground? 5 MR. HESTER: I think I have new 6 7 questions. I think I'm -- I'm questioning based on what Doctor Keyes says in her report. 8 9 MR. ARBITBLIT: Did you say anything 10 new in this report about Edlund that you didn't say 11 in the New York report? MR. HESTER: I haven't -- I haven't 12 13 prepared to go back to the New York report. focusing on what's in the West Virginia report 14 15 that's been submitted in this litigation and asking 16 questions about the scope of Doctor Keyes' opinions 17 in this litigation. And she talks about the Edlund 18 paper. 19 So Doctor Keyes, at page 19 of your report, 20 the bottom paragraph and then over to 20, this is 21 where you refer to the Edlund paper. Is that 22 right? 23 I just want to confirm, there are several 24 different Edlund papers that are cited, and I just

Page 50 want to make sure that we're --1 2 I hope I've got the -- I hope I've got the 3 right one. I thought I did, but confirm me on that. 4 5 So -- yes, I believe that's correct. Can you -- I mean, if you look at -- let's 6 7 see, the footnote -- Footnote 60 -- Footnote 60 in your report, you can see that you're citing to this 8 9 paper that we've got as Exhibit 10. Correct? 10 Α. Yes. 11 Ο. And so this is a study that involves 12 exposure to differing levels of prescribed opioids. Is that right? 1.3 That's correct. 14 Α. 15 Ο. And if you could look at page 562 --16 MR. ARBITBLIT: Counsel, I'm going to 17 stop the deposition now, and we're going to try to 18 reach Judge Wilkes. You're asking the same questions about the same articles, and I think it's 19 20 not okay. 21 If Judge Wilkes says it's okay, then I will withdraw the objections, but I don't want to 22 23 just proceed as if you can do this, which I 24 disagree with.

Page 51 So let's stop the deposition and see if 1 2 we can reach Judge Wilkes. 3 MR. HESTER: Okay. And I take it this doesn't count against our seven hours of time, 5 correct? MR. ARBITBLIT: That is correct, it 6 7 does not. So let's --MR. HESTER: All right. Doctor Keyes, 8 9 you can probably take a rest if you want. VIDEO OPERATOR: Going off the record. 10 11 The time is 9:53 a.m. (A discussion was had off the record 12 13 after which the proceedings continued as follows:) 14 15 VIDEO OPERATOR: This begins Media 16 Unit 2 in the deposition of Katherine Keyes. We're 17 back on the record. The time is 9:54 a.m. 18 MS. DO AMARAL: I can -- I can get him on my cell phone and just hold it next to the 19 microphone. I don't know if that's going to work. 20 21 Let's give it a try. 22 MR. HESTER: I quess we could also 23 call into a dial-in if you want. 24 MS. DO AMARAL: That may work better.

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Page 52
                  MR. HESTER: Well, let's see if we can
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     get him first, and then we'll figure out mechanics.
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                  MS. DO AMARAL: Okay.
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                  (A phone call was made to Judge
     Wilkes.)
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                  MS. DO AMARAL: I didn't reach him.
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                                                        Ι
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     did leave a message.
                  MR. ARBITBLIT: Is there someone at
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     his office who could be reached to find out whether
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     he's available? I don't want to keep counsel
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     waiting unreasonably if he's not going to be
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     available to get back to us shortly.
                  MS. DO AMARAL: I am not aware of
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     another way to contact him other than --
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                  MR. ARBITBLIT: Maybe try calling
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     those on the ground in West Virginia to see if they
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     have any insight on how to reach him.
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                  MS. DO AMARAL:
                                  Okay.
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                  MR. ARBITBLIT: Tim, we'll give this
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     about five or ten minutes. Is that all right?
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                  MR. HESTER: Yeah.
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                  MR. ARBITBLIT: And it's not counting
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     against your time.
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                  MR. HESTER:
                               Okay.
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Page 53 MR. ARBITBLIT: And I understand 1 2 you're doing what you think is your job; I'm just 3 doing what I think is mine. MR. HESTER: The -- I take it a 4 5 corollary in your position, Don, is you would agree that we can use everything that's been done in 6 relation to Doctor Keyes, any of her examinations, in New York, for instance, are available to us in 8 9 this case? 10 MR. ARBITBLIT: I would have assumed 11 that would be the case. I don't think that my 12 position on it matters. I think she was under 13 oath, her testimony could be used for the purposes that deposition testimony could be used in general. 14 15 Paulina, are you there? 16 THE DEPONENT: She's on the phone. 17 MR. HESTER: Don, I have -- I have 18 only a few more questions on this. I also want you to have in mind, she submitted a new expert report 19 in West Virginia. 20 21 I mean, she didn't stand on her New 22 York report; she submitted a new report. And it would --23 24 MR. ARBITBLIT: I -- sorry.

MR. HESTER: -- it seems -- it seems

that the position that you can't examine an expert

on a new report is really surprising to me. I -
it hadn't even occurred to me that you'd take this

position.

MR. ARBITBLIT: Well, Tim, it's a

little overbroad to say she submitted a new report.

I agree with you that there's a report signed

August 3rd, but if you compare certain sections of

the report, they're identical, and I haven't seen

study that she wrote in 2014 which isn't even in her report.

It's something that your partner, Paul

any different description of either the Edlund

study or the Vowles study, and certainly not the

So Rule 26 is specifically about experts, and the rule that I read earlier about duplicative testimony arises in that context.

Schmidt, brought up on his own.

Yes, she submitted a new report, but parts of it are identical, and there's no new report about Edlund, Vowles or the Keyes 2014 study. They're identical; they were the subject of prior discussion.

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Page 55 If we can't get Judge Wilkes, what I suggest is that we go back on but that I have a -if you would agree to a standing objection to the use of testimony gathered in this deposition based on documents that have been the subject of prior deposition, we could continue on that basis. I have no -- yeah. MR. HESTER: mean, I understand your objection. I just think when she submits a new report in a new case and she's purporting to offer opinions as to a new jurisdiction - namely West Virginia as compared to New York - I think we're entitled to examine her about it. I really have very little -- I have very little more that's going over this Edlund issue. MR. ARBITBLIT: Well, you know, I think --MR. HESTER: I think -- and then I think we transition on to stuff that's much more directly targeted on West Virginia issues. MR. ARBITBLIT: Okay. I have a list of articles that were the subject of prior inquiry.

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If you can tell me that they're not going to be

Page 56 part of today's inquiry, that would solve the 1 2 problem. MR. HESTER: I don't think I -- I 3 don't think I can tell you that articles aren't the 4 5 subject of inquiry. I can't -- I can't give you that broad a commitment. I think what I can tell 6 7 you is I'm focusing on what she's written in this report. That's all I focused on. 8 9 But T --10 MR. ARBITBLIT: Okay. Well, I 11 understand your position, and if you're agreeable to the standing objection and we can't get Judge 12 Wilkes promptly, then that's how I suggest we would 13 proceed. 14 15 MR. HESTER: All right. 16 MS. DO AMARAL: Gentlemen, I tried 17 other avenues and was not able to reach Judge 18 I have left him a message and left him my 19 cell phone number to return the call. 20 As I understand it, he is prompt in 21 doing so unless there is some other matter that 22 he's working on at that precise moment. So as we hear from him, I'll certainly let everyone know. 23 24 But at the moment, we are not able to

Page 57 reach him. 1 2 MR. ARBITBLIT: Tim, are you willing 3 to hold this Edlund topic in abeyance and go on to the other points that you said were not referring 5 to previous articles so that when Judge Wilkes calls back, we can advise him of the status as of 6 7 the time we're having this discussion? MR. HESTER: Yeah, I think I can hold 8 9 this in abeyance. 10 MR. ARBITBLIT: I appreciate that 11 courtesy. 12 Can we get the witness back in and if you want to put something on the record about this 13 now, we can, or we can wait until we have Judge 14 15 Wilkes. 16 MR. HESTER: Why don't we just wait until we have Judge Wilkes. 17 VIDEO OPERATOR: Okay. We've stayed 18 on the video record. Teresa, I'm not sure if 19 you've stayed on the record as well. 20 21 MS. DO AMARAL: We have Judge Wilkes. 22 THE COURT REPORTER: Yes, I've been on 23 the record the whole time. 24 VIDEO OPERATOR: Okay.

Page 58 MR. ARBITBLIT: Do we have Judge 1 2 Wilkes on the phone now? 3 MS. DO AMARAL: Yes, we do have Judge 4 Wilkes. I'm putting him on speaker. Judge Wilkes, can you hear me? 5 SPECIAL MASTER WILKES: I can. 6 7 MS. DO AMARAL: Counsel, can you hear him? 8 9 MR. ARBITBLIT: Yes. 10 MR. HESTER: Yes, we can. 11 MR. ARBITBLIT: Judge, this is Don 12 Arbitblit of Lieff Cabraser, one of attorneys for plaintiffs in the MDL. Good morning. I'm sorry to 13 disturb your day. 14 15 Counsel for defendants and I are 16 having a disagreement about the proper scope of 17 this deposition, and we'd just like a moment of 18 your time to state our positions and see whether we can get some resolution. 19 20 Briefly, our position is that a Rule 21 26(b)(2)(C) in the context of expert depositions 22 states, "On motion or on its own, the Court must 23 limit the frequency or extent of discovery 24 otherwise allowed by these rules if it determines

that the discovery sought is unreasonably cumulative or duplicative."

In this case, the witness is Katherine Keyes, an epidemiologist who has already been deposed in the MDL and in the New York case for a total of 14 hours.

The same firm, the same defendant, the same witness. We've had 50 minutes of testimony in which three of the four articles introduced on the examination were subject to inquiry in previous deposition testimony.

It is our position that this amounts to different answers about the same studies, that there was a full opportunity to depose on those subjects and the questions themselves are identical, and certainly the studies being asked about are identical, and we don't think that that's appropriate under Rule 26(b)(2)(C) to be going over old ground and seeking new answers to the same -- on the same studies.

That's our position. We would ask that

-- certainly the witness has submitted a new

report. However, as to these particular items,

there's been nothing new in the report, and

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particular studies by the Vowles, V-O-W-L-E-S, Edlund, E-D-L-U-N-D and a study the witness herself wrote that was not in her report but was used for impeachment by Mr. Hester's co-counsel at Covington. None of those have changed.

It's the same material, different questions, and we think it's not appropriate.

MR. HESTER: Judge Wilkes, this is Tim Hester, Counsel for McKesson from the firm of Covington & Burling. Doctor Keyes has submitted a new expert report in the West Virginia litigation. She's admittedly submitted expert reports in New York and in the Ohio litigation as well, but she's given -- she's given a separate expert report in the West Virginia litigation, and we are seeking to inquire into those opinions she stated in the West Virginia litigation, and there's not an intent to cover old ground, but we're focusing not on the New York litigation; we're focusing on the expert report she gave in this West Virginia case, and it seems to me we should be entitled to ask her a full range of questions about the opinions that she has given in the West Virginia litigation.

Some of those opinions involve

documents that were cited and relied on by her in the New York litigation as well, but here, we're seeking to develop testimony for purposes of the West Virginia litigation and the trial that's upcoming.

The standard articulated by counsel,
"unreasonably cumulative or duplicative" is not
applicable here in the sense that we're asking a
few questions about several documents that were the
subject of questioning in other -- in other
examinations previously of Doctor Keyes, but we're
not -- we're not engaged in unreasonably
duplicative or cumulative questioning.

We're asking about a new expert report and her opinions that she's providing in this litigation which should be viewed as distinct from what she has done previously in the New York or the Ohio litigation.

MR. ARBITBLIT: Judge, if I could just respond very briefly. The specific articles that are in question have nothing to do with West Virginia at all. They are generic to opioid use and there are public -- there are new opinions in the West Virginia report that we believe are fair

game for inquiry.

What we don't agree are fair game is going back to places in the previous reports where identical documents were addressed on a generic basis and were the subject of full inquiry.

There's plenty of new material that could -- could be the proper focus of discovery and inquiry, and we're not objecting to that. The mere fact that she submitted a new report does not mean that every sentence of it - when in fact, the vast majority of it - is the same as it was in the previous two, including the three articles that I just mentioned.

No changes.

SPECIAL MASTER WILKES: Okay. Well, I think one thing -- does someone want to add to that?

MR. RUBY: Judge, this is -- this is

Steve Ruby for Cardinal Health. I know this has

come up before with fact witnesses, a couple of

questions in that regard one -- in that situation

where there was a desire on the part of a party not

to have its fact witnesses redeposed, and I know

this may be something that's on your mind as this

issue comes up.

That was all handled well in advance of the deposition. The issue was raised, an order was entered by you that dealt with this ahead of time. And everybody had an opportunity to prepare for the deposition accordingly.

That hasn't been done here, and so it seems to me that the appropriate thing to do is to -- is to proceed with the deposition. If there are issues that need to be raised with Judge Faber relating to this testimony at trial, they can be raised then.

The other point that I would note is that the witness here is a -- is a retained expert witness, and so I think the calculation with respect to burden is a different calculation.

So as we sit here right now with Mr. Hester ready to take the deposition and having prepared for the deposition, it -- again, and having had no notice of these issues with respect to this witness - unlike the other situations that you've dealt with - I don't see -- I don't see any good reason not to be able to explore the studies that have been provided in her report, by -- she's

Page 64 provided in this --1 2 SPECIAL MASTER WILKES: I'm losing you 3 there a little bit, Mr. Ruby. I'm sorry. Could 4 you repeat what you said? 5 MR. RUBY: Yes, Judge, I -- I was just summarizing there at the end, given the fact that 6 7 these -- this hasn't been raised in advance of the deposition, Mr. Hester has prepared to take the 8 9 deposition based on the fact that the witness has 10 submitted an expert report in this West Virginia 11 litigation that cites these studies, and this is a 12 -- a retained expert who has proffered her opinions 13 specific to this West Virginia litigation. It seems to me that this is different 14 15 from the situations where you have imposed 16 limitations in the past, and the appropriate thing 17 to do is to let the deposition go forward and to 18 address -- to let Mr. Hester address the studies that, as I said, have been cited in the report that 19 20 was produced specifically in this West Virginia 21 litigation. 22 MR. ARBITBLIT: May I briefly be 23 heard, Your Honor? 24 SPECIAL MASTER WILKES: Sure.

Page 65 MR. ARBITBLIT: I think that the 1 2 Federal Rules of Civil Procedure provide all the 3 notice that any party could ever ask for, and the -- what they specifically say in the context of experts, under Rule 26, is that duplicative --5 "unreasonably cumulative or duplicative discovery 6 7 must be foreclosed." "The Court must limit." It's not 8 9 "shall" -- it's not "may." It's "must." So I 10 don't know what further notice could be required. 11 I didn't -- I certainly didn't come 12 into the deposition thinking that Mr. Hester was 13 going to plow old ground and try to elicit new answers. And I don't think -- certainly Mr. Hester 14 15 during the break has said that he has other 16 subjects that are not cumulative and duplicative of 17 previous depositions, and the witness has a report 18 that includes quite a bit of West Virginia-specific 19 information which is a fair target for his inquiry: 20 SPECIAL MASTER WILKES: Okay. Go 21 ahead. Were you cut off? MR. ARBITBLIT: No, I'm done, Your 22 23 Honor. Thank you. 24 SPECIAL MASTER WILKES: Okay. Well,

Page 66 two things. I think that we need to -- we need to 1 2 keep in mind here. Number one, we have an overall 3 limit as to the time of the deposition, so how -how a party wants to use that time - whether they 5 feel, you know, it's more fruitful to use it rehashing some other stuff - is one consideration 6 7 and anticipating that you guys, you know, your seven hours is going to be used discussing 8 9 something. 10 I think in prior -- prior instances, 11 we've had similar issues and, you know, it's limited to the quality of the time used in the 12 13 limited quantity of time, number one. Number two -- and I am mindful of 14 15 plaintiff's concerns because we have direction from 16 the Court that discovery is to be limited to unique 17 issues to this case, because of the vast majority 18 of discovery having already been done in the large MDL that's seeking to be limited to unique 19 jurisdictional issues. 20 21 I don't think that because it's a 22 report submitted in this case that automatically 23 opens up that -- all inquiry to the same issues 24 that may have been gone over previously, so the

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ruling for today will be that in such ways as the expert's opinion differs -- her testimony today differs from previously-given testimony, it's fair game and can be inquired into.

So you have to do a little bit of inquiry on certain issues: "Does your opinion differ" or "How does it apply to the West Virginia case?" And then that's fair game.

But I think we have an overriding Court Order limiting discovery that's unique to the jurisdiction -- jurisdictional issues. So hopefully that will narrow it down some in that the general subjects that have already been inquired into in the MDL should not be rehashed unless there is some difference unique to the Cabell County/Huntington jurisdictional issues.

MR. HESTER: Judge, this is Tim

Hester, counsel for McKesson. Let me just ask for
a clarification, though, on one point. I

understand -- I understand Your Honor's ruling in
relation to a particular document that may have
been discussed or the subject of examination in a
prior deposition of this witness.

Does that make it clear?

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But there are a number of opinions that this witness is expressing that relate to activities in West Virginia that might also relate to activities in other jurisdictions. For instance, the supply of opioids. She's providing opinions about supply of opioids in West Virginia. There's parallels to things she has said about New York or Ohio, but it does seem to me we need to be able to inquire into her opinions on issues that relate to West Virginia, even if there's a parallel or analogous set of opinions she's provided as to New York or Ohio.

I wanted to understand if the Court has that in mind, as you state your ruling here.

absolutely, you're entitled to inquire as to that which goes into West Virginia, even if it's the same opinion as in the others, because I think the burden -- plaintiffs still bear the burden of proving the nuisance in West Virginia, and these are events that are fact-specific to West Virginia so certainly you're entitled to inquire into that.

MR. ARBITBLIT: Can I ask, Your Honor, whether it would be appropriate to have -- in the

case of material or questioning that's been raised in prior cases as a preliminary question from defense counsel, "Does your opinion concerning this have any different impact or meaning for the West Virginia case compared to the Ohio case or the New York case?"

And I would submit that in the three instances we're talking about, the language of the report is identical; the cases -- they don't have any bearing on West Virginia or Ohio or New York or any specific jurisdiction; they don't have a bearing on Mr. Hester's concern about the opioid supply to Cabell/Huntington, and the answer would be no, they don't have any different meaning in this case than they had in the previous.

So rather than allowing a blanket

"Let's just inquire and see what we find out how it
applies to West Virginia," if there's a preliminary
question to the witness, "Does your opinion in the
West Virginia case change based on this particular
article, does it have any bearing on West Virginia
specifically, and if so, what," I think that would
address both concerns.

We wouldn't get a rehash of things that

are generic to opioids nationwide or data analysis of rates of OUD nationwide, and we would allow defense counsel to inquire as to anything that's jurisdiction-specific.

MR. HESTER: Well, Your Honor, this is Tim Hester. If I could be heard on that point.

It's a little hard -- it's a little hard to be that precise, to articulate a point that the witness then agrees or disagrees is different or not different from what she said in New York or Ohio.

It seems to me we need to be able to inquire into certain topics and ask questions that allow us to explore the basis for her opinions on issues that relate specifically to activities in West Virginia.

She's talking about things such as supply of opioids in West Virginia; she's talking about issues involving heroin and fentanyl use in West Virginia. We should be able to ask her about those subjects, whether or not she gives a generalized answer that she has a parallel view on New York and Ohio, because she's providing testimony that relates specifically to the circumstances in West Virginia, even if there's

parallel or analogous views that she has in other jurisdictions.

MR. ARBITBLIT: And with all due respect, Your Honor, that would be an exception that swallows the rule that Your Honor just stated. There's nothing in what Mr. Hester just stated generically that applies to the articles that have come up. There were no questions about how this bears on Cabell County or Huntington; they were generic questions about rates of OUD or misuse in general. They had --

There wasn't -- if you look through the transcript, there wasn't a mention of West Virginia once in those questions about these articles. So basically he's trying to make up an exception that would allow him to do exactly what he was planning to do all along.

special Master Wilkes: Well, we're moving forward. I don't have the transcript in front of me. I don't know what those questions were. But moving forward, they are going to be --they have to be jurisdictionally-specific.

And I -- I surmise that the opinions -- the expert's opinion is not going to change in

Page 72 regards to the cause and effect or remedial aspects 1 2 from any of the jurisdictions. But defendants are 3 entitled to inquire specifically as to that cause and effect in West Virginia, because they have to defend against proving what have -- you know, that 5 their actions were the cause of, contributed to 6 7 what plaintiffs allege in Cabell/Huntington. So what he asked previously, I can't --8 9 I'm not going to comment on. But moving forward, 10 it is going to have to be somewhat premised with the inquiry as to "How did this affect, or how did 11 12 this apply in Cabell/Huntington, and does it differ 13 from the testimony previously given on any other points." 14 15 MR. ARBITBLIT: And just to -- go 16 ahead, Your Honor. 17 SPECIAL MASTER WILKES: 18 jurisdictionally specific. 19 MR. HESTER: But -- Your Honor, this is Tim Hester again for McKesson. And just to go 20 21 back to a point that Mr. Ruby had made that I do want to reiterate: This was -- if the plaintiffs 22 23 were taking this position - which frankly is a 24 surprise to us - we have expert -- we have expert

reports submitted in West Virginia that obviously have overlaps with expert reports submitted in New York or Ohio.

We were not aware until the midst of this deposition that the plaintiffs were taking the position that if there's some duplication - in other words, if the witness copied something out of her New York report and put it into West Virginia - that somehow we -- we're not entitled to inquire into it because it's, quote, the same.

We're being put into a position in the midst of a deposition, having to sift out what is new or what is different from what was previously submitted by this witness. That seems too high a burden for an expert report, that we have to go back and figure out what she previously said in other jurisdictions and then parse through how we differentiate.

This -- as Mr. Ruby pointed out, when this has come up previously, it was in the context of fact witnesses, but it was done in advance of the deposition so there could be an opportunity to plan.

If the plaintiffs were taking this

Page 74 position, we were certainly not apprised of it. 1 2 And so we're really put in a -- in a very difficult 3 - and I think prejudicial - situation here, Your Honor. 4 SPECIAL MASTER WILKES: Well, I think 5 you should have been on notice of it because of the 6 7 order that said discovery is going to be limited to fact-specific and not duplicative of what took 8 9 place in the other MDL actions. So -- you know, 10 that's just been the general trend through the 11 whole matter. 12 I understand it's an expert and there's 13 more leeway there, but it is still discovery. So -- you know, I think everyone has been cognizant --14 15 or should have been cognizant of that limitation. And in the fact witnesses -- in fact, 16 17 all that was done is reiteration, the fact that 18 it's going to be oftentimes geographically limited. Some, I think -- and I'm thinking back, even 19 geographically limited as to the facts and 20 21 discovery occurring into West Virginia. So I don't think you're prejudiced by 22

the fact because you have that information that you're inquiring again. If there's something new

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that's specific to West -- to this case, then you're entitled to inquire that way.

I'm not in any way saying you're precluded from asking how the application of that opinion applies to West Virginia or applies to this case, but if the -- if the witness says, you know, "I opined X and Y equals Z in the New York case" or "on another case" and then the next question is, "Well, is there any -- does it have any different application to West Virginia?"

If they say, "No," then you live with that opinion because it's -- you previously had the opportunity to flesh it out.

So I don't think it's prejudicial whatsoever, and you know, I just think that we have to be cognizant of the fact that we're -- we're looking at a specific jurisdiction for the elements of proof here, and that's what the discovery - even experts - should be limited to.

MR. HESTER: Well, Your Honor, I mean, I understand your position, and just to state our position on the record so it's clear, we understood the limitations on fact discovery, but to our knowledge, those have not been applied to expert

opinions.

This is an opinion she's stating in this litigation, and we're not being permitted to inquire fully into it. It's not the same principle as -- as fact discovery where there was an effort to avoid duplication of facts.

This is the expert opinion that's being offered in West Virginia, and we're now being told in the midst of the deposition that we have to sift through and figure out what -- what she copied from her report out of New York or Ohio and what is new.

That's a -- that's a quite difficult standard to abide by, and it puts us in a prejudicial position that's different from a fact witness who's not subject to redeposition on the same facts.

This is an expert opinion being offered by a retained expert, and we had not understood that there would be this suggestion that somehow if she had a passage in her report in New York that she has copied into her West Virginia report that somehow we're precluded or limited in what we can ask about that opinion in West Virginia.

So with respect, Your Honor, I would

Page 77 view this as -- or would submit it should be viewed 1 2 as different from the -- from the way in which the Court has handled fact witnesses. 3 SPECIAL MASTER WILKES: Well, on that 4 5 subject, explain to me why it is different information that you've not already had the 6 7 opportunity to inquire into. MR. HESTER: Because her opinions 8 9 relate -- they may be a generalized opinion that has a general background or predicate that is 10 comparable to what she said in New York or 11 12 comparable to what she said in Ohio, but it has applications to this community that are different. 1.3 14 The implications --15 SPECIAL MASTER WILKES: Well --16 MR. HESTER: Go ahead. 17 SPECIAL MASTER WILKES: I think you're 18 not -- you're not understanding me. You're entitled to inquire to that, how it is different in 19 -- to this litigation. You're entitled to make 20 21 that inquiry. 22 MR. ARBITBLIT: And if the witness 23 says it's not different, then the inquiry is 24 foreclosed. Correct, Your Honor?

Page 78 MR. HESTER: Well, Your Honor, that's 1 2 -- we need -- we need to have some leeway here to 3 be able to ask her threshold questions to build up to the West Virginia-specific pieces. We can't be precluded from a subject just because she says, "I 5 have a general view that is the same." 6 7 Because the general view needs to be applied in relation to the West Virginia-specific 8 9 facts. 10 SPECIAL MASTER WILKES: So ask her 11 that. Ask her how her general view applies to West Virginia facts. But that general view, you've 12 13 already had the opportunity to inquire into. MR. HESTER: Well, but, Your Honor, 14 15 I'll give you a specific example. She was asked 16 about -- she was asked about a paper that she wrote 17 on -- on the use of opioids in rural communities, 18 and she was asked about that in New York. It's one of the papers that counsel objected to my asking 19 20 her about today. 21 In the New York litigation, she said, "Well, I don't know whether this is really a rural 22 23 area to which this would apply." 24 I mean, we need to be able to have a

Page 79 little room to maneuver, is all I'm suggesting, to 1 2 build some basic questioning about elements of her 3 opinion that then allow us to get to West Virginia-specific facts. What I'm concerned about is we're gonna 5 be put in a posture where we have to ask her a 6 7 generalized question, "Is your view on a certain subject the same or different in West Virginia?" 8 9 You -- we need to be able to ask her the general 10 questions about the subject in order to get to the 11 specific questions about West Virginia. I -- we shouldn't be precluded from an 12 13 area of inquiry simply because her view on the general topic is the same as in New York or Ohio 14 15 because we need to ask the general questions to get 16 to the specific new West Virginia questions. 17 MR. ARBITBLIT: Your Honor, that's a 18 very misleading reference to the article that 19 Mr. Hester just made. 20 MS. DO AMARAL: Hang on, Don. 21 SPECIAL MASTER WILKES: Hold on. 22 do you have to ask the general guestions if the 23 inquiry is, "No, my view's not different"? 24 MR. HESTER: Your Honor, because --

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     because it's more nuanced than that. It's not as
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     simple as, "Did the car go through the red light?"
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     It -- these are very subtle points that she's
     testifying to.
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                 We have to have a common understanding
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     on the general points to -- in order then to be
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     able to ask her specific questions about how that
     applies to West Virginia.
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                 What I'm concerned about is that we'll
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     be put in a posture where in the midst of this
     examination, she says, "Well, my general view" on
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     X, Y, Z subject --
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13
                  (Random overtalk from someone with
     their sound not muted.)
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15
                  MR. HESTER: I think somebody is on
     the line --
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17
                  MR. RUBY: I think somebody is on the
18
     call --
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                  MS. DO AMARAL: Mr. Ruby? I think you
     may need to mute your phone.
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21
                  MR. RUBY: No, not me. I was pointing
     out that somebody was on a call on the other line.
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                  MS. DO AMARAL: Apologies.
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                  MR. ARBITBLIT: Your Honor, if I may,
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the article that Mr. Hester referred to about rural/urban differences, his question had nothing to do with the aspects of that article. Instead, it was the identical question that was raised by his partner Paul Schmidt in a previous deposition about whether opioids are effective for chronic pain based on one sentence that the witness has written in 2014.

It was the identical question, seeking a different answer, and it had nothing to do with West Virginia. The sentence is, "When used as prescribed under medical supervision, opioid analgesics are effective and used as standard practice in managing acute and chronic pain."

That was the sentence that counsel read to her. Had nothing to do with West Virginia or rural/urban differences. It's the same quote that his partner pulled out of this six-year-old article less than six months -- or eight months ago in another deposition and it -- that's a perfect example of why they shouldn't be allowed to plow old ground.

MR. RUBY: Judge, this is Steve Ruby again. I think -- and I don't want to put words in

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Mr. Hester's mouth, but I think what he is saying is there will be situations in the course of this deposition where he needs to lay foundation for West Virginia-specific questions, where it's not possible to simply jump in and say, "Do you agree that -- that this applies to West Virginia" where in other words, there will need to be some foundation laid as to what this is. So you can imagine a series of questions along the lines of "You agree" -- or "It is your opinion that the supply of opioids functions in X manner, and the basis for that opinion is Y, and so on and so on, leading up to what I think everyone agrees would be a necessary and appropriate question, which is "Do you -- is it your opinion that the supply of prescription opioids functions in the same manner in West Virginia and that it functioned in the same manner with respect to Cabell County/Huntington, how is it that you've reached that conclusion and what do you base that on?" And correct me if I'm wrong, but I

And correct me if I'm wrong, but I
don't take your ruling to be so broad as to
preclude good faith foundational questions that are
necessary in order to -- in order to establish or

Page 83 permit the asking of the West Virginia-specific 1 2 questions. 3 MS. DO AMARAL: Mr. Ruby, it's getting harder to hear you. 5 MR. RUBY: Judge, does that -- did you catch all that? 6 7 SPECIAL MASTER WILKES: I caught most of it, and actually, Mr. Ruby, as you often do, you 8 9 put it in better words than I do. That's exactly 10 right. I understand you're going to have to make some inquiry to make the determination as to 11 whether or not it is jurisdictionally unique, and 12 13 that's allowable. What is not is just to go back and 14 15 knock out -- attempt again to rehash the general 16 basis of the opinions that have been subject to inquiry at previous depositions. 17 18 That's the duplicative part. understand that you have to lay a foundation, you 19 have to lay a basis to get into whether or not 20 21 there is a difference, and that is correct, and I think there can be -- and that's fair game. 22 23 Because there could be an inquiry as to 24 the knowledge of the jurisdiction and why the

expert opines that that previous opinion they hold, why it's applicable to this jurisdiction that's a part of this lawsuit.

So yes, I understand that. What I want to get away from is just a rehashing and reinquiry of the previous depositions. But yeah, there has to be some leeway in setting the foundation, and it's only fair to the witness also to let them have an opportunity to explain how they feel it's applicable or not to this jurisdiction.

So I think Mr. Ruby gets -- gets it.

MR. ARBITBLIT: Your Honor, if I may, this is Don Arbitblit again responding to that.

Again, I don't want the foundation exception to swallow up the rule and have Mr. Hester asking all the questions he planned to ask and then at the end of his sequence of questioning ask, "How does this apply to West Virginia?"

We're talking about articles that, by and large, the literature that the witness -- if the witness relied on something that's specific to West Virginia, it's fair game. But if the witness -- as is the case with what's been raised previously and as is the case with the vast

majority of her references in her report, they're national studies. They're studies of populations that -- that inform her opinions.

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If the initial foundational question should be, "Do you have any opinions about this study that are specific to West Virginia?" That would abide by Judge Faber's order and with Your Honor's formulation of the question that this needs to be jurisdiction-specific.

The foundation isn't, "Did this study say X, Y and Z and did this study relate to incidence or prevalence or did this study relate to the misuse or opioid use disorder," which are all generic questions that have been asked in this deposition about materials that are not specific to West Virginia.

So to the extent foundation is that question, do you have any opinions about this article that are specific to West Virginia" as opposed to generic to your overall opinion, then fine, ask the question and the witness can answer it. And if the answer is "Yes," then you can proceed with further questioning.

But if the answer is "No," it's the

Page 86 same as it would have been in the previous 1 2 litigation at the time of the previous deposition, 3 then, I -- I don't see how that type of inquiry would abide by Judge Faber's ruling or your own. 5 MR. RUBY: But Judge, I think that -with due respect to opposing counsel --6 7 MR. ARBITBLIT: The judge is speaking, Steve. 8 9 SPECIAL MASTER WILKES: I'm not far 10 off on that at all. But there also has to be the 11 ability to inquire as to why you don't think it is, 12 just as if there is the urban/rural difference or 13 something else. There has to be -- there has to be the 14 15 ability to inquire in regard to -- to some 16 hypothetical that may be posed as to, "Well, why do 17 you not think it's applicable here because we have 18 a rural community or we have an urban community," so I can't limit it just to -- to a "No," but they 19 also have to have the opportunity to inquire as to 20 21 why they don't think it's applicable or why it is. But besides that, I agree with you. 22 23 The foundation can be very limited in regards to 24 these studies.

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MR. HESTER: But yet, Your Honor -this is Tim Hester again. Just to make sure I
understand the scope of what you're saying, that
setting the foundation about her opinion on a
subject requires some questioning about her views
that may be general, but then lead to the West
Virginia-specific points.

And I just want to make sure I've got the ability to ask her questions about her general view on certain points and then to turn to West Virginia.

I don't want to have to cut off the entire inquiry simply because her general view is the same as her general view in New York and Ohio.

I need to be able to set that foundation before I then ask her the West Virginia-specific pieces of it.

MR. ARBITBLIT: That is exactly the opposite of what is necessary. That is exactly the exception trying to swallow the rule. That is exactly trying to ask the same questions about the substance of the article in question rather than asking whether it has any bearing on West Virginia.

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SPECIAL MASTER WILKES: Have you guys

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-- have you guys ever heard of the old phrase about choking on a gnat and swallowing a camel? Because I -- because I think that's where we've gotten.

Whether the substance swallows the rule or not, you know, the law's a wonderful thing and it's a search for the truth, and you scratch your head and wonder why there are a thousand and one exceptions to this ability.

But -- here's the general thing: You guys know what I'm saying. It has to be fact -- you have to be able to map it into jurisdictionally-specific continued discovery and inquiry.

Now, whether you want to call it foundational or whether you want to call it at the end of, you know, the witness saying, "Yes, I think it applies" or "No, I don't," then asking the question after that, that's fine. I don't care.

But the premise of it is: You don't have to rehash the validity and the formulation of the opinion, but you can inquire as to the application of that opinion to West Virginia, and you could inquire as to the expert's reasoning for maintaining that opinion in this case or not

Page 89 maintaining it. 1 2 But the opinion has been inquired into 3 previously. That's been the subject of previous depositions. So that -- it then becomes cumulative in this case. 5 So we have to hone it down to be a 6 7 little more to its application to this specific jurisdiction, this specific case. 8 9 So if there's a report as to the 10 number or frequency of opioids distributed in 11 Cabell/Huntington and you can say, "Does that opinion that you formed from this national report" 12 or "you've taken from this, does that apply here in 13 Cabell/Huntington in this case?" 14 15 "Yes." 16 "Well, why?" And then they can explain specifically, 17 18 jurisdictionally-specifically. Or if they say, "No," you can say, 19 20 "Well, why," and then you can inquire as to the 21 difference. 22 That's what I'm saying. So we don't need to -- let's not get too formed up into the 23 24 rule and all. But if it's been inquired into and

Page 90 it's a basic opinion, then that's off limits. 1 2 That's duplicative. 3 If it can be specifically inquired into, yes, and its application in this case. And that's as clear as I can make it. 5 MR. ARBITBLIT: Thank you, Your Honor. 6 7 May I assume that the same ruling applies to the deposition of another witness who's also been 8 9 subjected to 14 hours of deposition testimony that's coming up on Thursday? 10 11 SPECIAL MASTER WILKES: I would hope 12 so, but you know -- it's not -- it's not unique to 13 these. It's been a trend that's gone on through the discovery, whether it be written or deposition 14 15 discovery, and I think it needs to continue 16 through. 17 If there's specific problems, give me a call, I'll do my best to try to resolve them. 18 19 basically, yes. 20 And it goes to both plaintiffs and 21 defendants. If it's been inquired into -- and it's 22 what I'm going to call a "general opinion," then we 23 should gloss over it and move into 24 jurisdictionally- specific application of those

Page 91 opinions. 1 2 MR. ARBITBLIT: Your Honor, there's an 3 article pending at the time of this call by Edlund, which was a study that wasn't West Virginia-4 5 specific. It was a study of the incidence of various degrees of exposure and duration to opioids 6 7 and what incidence of OUD resulted. I would assume based on this discussion 8 9 that the next question that Mr. Hester asks of the witness should be "Does your opinion about the 10 11 Edlund study change based on the fact that this 12 case is in West Virginia as opposed to New York or Ohio?" 13 And if she says, "No," then that should 14 15 be the end of it. And I'm assuming also that Mr. Hester disagrees with me, and I'd rather hash 16 17 this out now than have to get back on the phone with you. 18 19 SPECIAL MASTER WILKES: Well, let me 20 ask this question, because the answer -- it will 21 quickly maybe resolve it. Was that study published 22 prior to any of the -- this expert's depositions 23 previously? 24 MR. ARBITBLIT: Yes. It's a 2014

Page 92 study. 1 2 SPECIAL MASTER WILKES: Okay. So why 3 would that change? MR. ARBITBLIT: I'm sure -- I'm sure 4 it hasn't. That's the whole --5 MR. RUBY: 6 Judge --7 SPECIAL MASTER WILKES: Okay. Judge, it seems to me that 8 MR. RUBY: 9 it doesn't need to be -- based on the ruling that you've made, it doesn't need to be that 10 11 restrictive. And I think as you said at the 12 beginning, we have a limited amount of time, and if 13 Mr. Hester wants to ask 50 questions about various 14 variables that are related to West Virginia, "Did you consider this aspect of the situation in West 15 16 Virginia, " "Did you consider that aspect, " I don't 17 think there'd be any prohibition on asking those 18 questions simply because the witness is a very high 19 level know as to whether she has any different 20 opinion relating to West Virginia. 21 I think we're absolutely entitled. 22 think I heard you say that we're entitled to probe the bases for the witness' conclusion or the 23 24 witness' rendering of the same opinion with respect

to West Virginia.

And I think that is important here, and it's important to recognize that plaintiffs -there's some substantive advocacy here just beyond
the procedural point that we're address, because
plaintiffs want to take the position that -- that
-- and are in this discussion, taking the position
that all these national studies apply with complete
force and validity to West Virginia.

We don't take that position at all. We think that there are important aspects, important facts and variables specific to West Virginia and specific to Cabell and Huntington that have to be addressed, and I did not understand at all your ruling to be that if Mr. Hester asks the question, "Is there any difference in your opinion on this study because this case is in West Virginia" and the witness says, "No," that we don't get to further probe the basis for that answer.

MR. ARBITBLIT: That's just so disingenuous, Steve. I mean, you were on the deposition. Not one word was mentioned about West Virginia in relation to Vowles, Edlund or Doctor Keyes' prior article, the three that we're talking

about, and so it's -- it's making up a reason after the fact.

There was no discussion of West

Virginia in relation to those articles because

there -- their discussions of whether opioids lead

to misuse, opioid use disorder and how much of a

dose and duration will lead to what levels of

opioid use disorder, which are the same for people

whether they're in West Virginia, Montana, Ohio,

wherever it happens to be.

And to say that their questions should go on about West Virginia ignores what just happened. These are not West Virginia-specific.

To the extent there's West Virginia-specific material - which is extensive - in the witness' report, why not ask your questions about that?

SPECIAL MASTER WILKES: Well, they get to ask their questions and use their allotted time the way they want, like I -- like I said earlier.

If they choose to use it in a way that's not advantageous to them, then let them fall on their sword. You're gonna be there for seven hours no matter what. I don't care -- you know, we

Page 95 -- we know that's what's going to take place, so I 1 2 have to give them some leeway as to ask questions 3 they want, and if it is specific as to West Virginia and they want to -- they want to know why 5 it is or is not applicable to West Virginia, they're entitled to ask that, that side of it. 6 7 That's, I think, what Mr. Ruby is saying, and I have to agree with him there. But 8 9 what I -- what I won't allow is inquiry in regards to that which has previously been testified to on 10 -- on a defendant. But once it's -- once the that 11 12 threshold that it's not applicable to West Virginia 13 or why isn't it, then that's where the questioning has to stop -- or it is and why is it. 14 15 Call it foundational or call it 16 subsequent questioning -- you know, this report has -- the premise of this report is X. "Is it 17 18 applicable to West Virginia?" "Yes." 19 20 "Well, why is this applicable to 21 Cabell/Huntington"? You know, or "The premise of this report is Y, is it applicable to West 22 Virginia?" 23 24 "No."

Page 96 "Well, then why isn't it applicable to 1 2 West Virginia?" 3 And then I think they're entitled to make that inquiry. Because --4 5 MR.ARBITBLIT: I agree with Your Honor. I agree. I wasn't challenging that aspect. 6 7 I just don't want a substantive reexamination of the witness on the details or cherry-picked quotes 8 9 from articles that have been the subject of prior 10 inquiry before we get to the jurisdictional question, and that's --11 12 That's what I think is improper. 13 think -- I agree with you if the -- if the witness says "It does apply for the same reasons as 14 15 previously stated" or "It doesn't apply and here's 16 why," let them ask those questions. 17 But what's improper is going through -18 as they've done so far - the substance of the 19 articles that have been the subject of prior inquiry and eliciting new testimony on things that 20 21 have been inquired about before without any reference at all to West Virginia in the questions 22 23 or the answers. 24 SPECIAL MASTER WILKES: Well, I think

it's clear -- I've made clear that, you know, we're not gonna have just duplicative examination of opinion previously tested by deposition. But the application to West Virginia and why or why not it applies is fair game.

I don't know how to make it any clearer than that.

MR. RUBY: Judge, I -- thank you,

Judge. And I don't want to beat a dead horse, but

I think -- and I can assure you that we will -- I

think I understand what you are saying. I can

assure you - and I think I can speak for Mr. Hester

in saying - that we will certainly proceed in good

faith reliance on the ruling.

I think what -- may be one way of expressing what the Court is saying is that there are going to be general attacks on general opinions on which the witness has been previously questioned, but we can discuss those previous general opinions to lay foundation for West Virginia-specific questions and make sure that we have an understanding of what the previous opinion is so that we can ask the West Virginia-specific question and we can make West Virginia-specific

Page 98 attacks or ask probing West Virginia-specific 1 2 questions to challenge previously-expressed general opinions. 3 Is that all fair to say, Judge? 4 SPECIAL MASTER WILKES: I think so. 5 It's a lot to digest, but I think that is correct, 6 7 in that -- you know, it ties it into being jurisdictionally-specific in its application in 8 9 this case in this jurisdiction, yes. And if there's a question, call me. 10 Ι 11 understand both sides' position on it. I think 12 I've been clear, but if -- you know, I understand 13 there also may be some -- some testing of it that has a -- may have some objectionable sides, and if 14 15 that's the case, just give me a call. And I think it would be easier to put 16 17 out the brush fires now that we've put out the main 18 one. 19 Thank you, Your Honor. MR. HESTER: 20 MR. ARBITBLIT: Thank you, Your Honor. 21 MR. RUBY: Thank you, Judge. SPECIAL MASTER WILKES: Uh-huh. 22 23 Bye-bye. 24 (Phone call with Judge Wilkes ended.)

Page 99 MR. HESTER: Should we take a break? 1 2 MR. ARBITBLIT: If you need one, take 3 one. MR. HESTER: I know we've had the 4 5 witness sitting for a while. Can we just take a five-minute break, Don, and then we'll -- let's 6 7 resume at five past 11:00. Okay? MR. ARBITBLIT: Okay. 8 9 VIDEO OPERATOR: Going off the record. The time is 10:58 a.m. 10 11 (A recess was taken after which the proceedings continued as follows:) 12 13 VIDEO OPERATOR: Now begins Media Unit 3 in the deposition of Katherine Keyes. We're back 14 15 on the record. The time is 11:07 a.m. 16 BY MR. HESTER: 17 Doctor Keyes, before we took -- excused you Ο. from the deposition for a while, I had been asking 18 you about the Edlund study, Exhibit 10. Do you 19 have it there in front of you? 20 21 Α. This is Edlund 2014. Yes. Yeah, Exhibit 10. 22 0. 23 Α. Yes. 24 Q. And do the -- do the findings of that study

Page 100 apply to West Virginia, in your view? 1 2 Α. Yes. 3 Ο. Okay. Let me ask you to look at Exhibit 46, please. And for the record, Exhibit 46 is a 5 paper by Sean McCabe and others, A prospective study of nonmedical use, prescription opioids 6 during adolescence and substance use disorder 7 symptoms in early mid life. 8 9 KEYES DEPOSITION EXHIBIT NO. 46 10 ("A prospective study of nonmedical 11 use of prescription opioids during adolescence and subsequent use 12 13 disorder symptoms in early midlife" by 14 McCabe, et al. dated 1-1-19 was marked 15 for identification purposes as Keyes Deposition Exhibit No. 46.) 16 17 Doctor Keyes, have you seen this study Ο. before? 18 19 Α. Yes. 20 And let me ask you to look at page 7 of the 21 document. And under Heading 3.2 - I guess it's the 22 fifth paragraph down - there's a statement, "Adolescents who indicated medical use without a 23 history of NMUPO did not differ from adolescents 24

Page 101 with no history of medical use of prescription 1 2 opioids or NMUPO in the odds of AUD, CUD, ODUD and 3 any SUD symptoms." Do you see that sentence? 4 5 MR. ARBITBLIT: Objection. That's the identical question asked about a non-West Virginia 6 7 study in a prior deposition. Can you just ask the witness whether opinions on --8 9 MR. HESTER: That's my next question, 10 Don. I'm just going to ask her one question, which is whether they apply -- I can't ask her the 11 12 question unless I can point her to a place that I'm asking her about. 13 MR. ARBITBLIT: Thank you. 14 15 Ο. Do you see that sentence, Doctor Keyes? I do. 16 Α. 17 Does that apply to West Virginia, in your Q. 18 view? 19 MR. ARBITBLIT: Objection. Vaque. 20 Yeah, I -- can I just request a bit more Α. 21 clarification? Yes. Does that -- does that statement 22 Ο. 23 apply to West Virginia, in your view? 24 MR. ARBITBLIT: Objection.

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- A. Does the statement apply to West Virginia?

 I mean, I would -- I would take issue with the statement.
- Q. Excuse me? I'm sorry. I didn't understand what you said. You said you'd take issue with the statement?
- A. Well, the -- I believe that the study results generalized West Virginia.
- Q. Okay. Maybe that's a better way to put it.

 Do you agree that the findings stated in this

 sentence generalized to West Virginia?
- A. Actually, I'm sorry, can I -- I -- can you repeat the question?
- Q. Yes. Do you agree that the findings stated here generalizes to the population of West Virginia?
- MR. ARBITBLIT: Object to form.
- 18 A. Find -- I'm sorry, I'm just having trouble

 19 with --
 - Q. -- the word "generalized?" Maybe I can ask it another way. Do you agree that this finding applies to the population of West Virginia?
- MR. ARBITBLIT: Object to form.
 - A. I don't -- I don't agree with the author's

Page 103 -- as I've stated in other depositions, I don't 1 2 agree with the author's general description of the 3 results, so I wouldn't want to say that the findings -- that this statement generalizes to West Virginia. 5 6 Q. You don't agree with the statement, you 7 mean? Α. That's correct. 8 9 Q. Let me ask you to look at Exhibit 9, 10 please. Do you have Exhibit 9 there? 11 I do. Α. For the record, Exhibit 9 is a paper 12 Ο. 13 written by Nora Volkow and Thomas McLellan, Opioid Abuse and Chronic Pain - Misconceptions and 14 15 Mitigation Strategies from the New England Journal of Medicine. 16 17 KEYES DEPOSITION EXHIBIT NO. 9 18 ("Opioid Abuse in Chronic Pain -19 Misconceptions and Mitigation 20 Strategies" by Volkow and McLellan 21 dated 3-31-16 was marked for 22 identification purposes as Keyes 2.3 Deposition Exhibit No. 9.) Doctor Keyes, have you seen this document 24 Q.

Page 104 before? 1 2 Α. Yes. 3 Q. And I wanted to point you in the first paragraph under SOURCE OF THE OPIOID EPIDEMIC, I 4 5 wanted to point you to the third and fourth sentences. It says, "In 2014 alone, U.S. retail 6 7 pharmacies dispensed 245 million prescriptions for opioid pain relievers, " and then it goes on to say, 8 9 "Of these prescriptions, 65% were for short-term therapy (less than 3 weeks)." 10 11 Do you see that? 12 Α. I do. 13 Do you have an understanding that that percentage, 65 percent of prescriptions for 14 short-term therapy, applies to the West Virginia 15 16 community? 17 I don't have data on that topic. 18 So you don't know one way or the other what Ο. the percentage is in West Virginia of prescriptions 19 written for short-term therapy? 20 21 Α. No. 22 Okay. Let me ask you to look at page 22 of 23 your report, please. And in your report, at page 24 22 and elsewhere, you describe the way that

Page 105 exposure leads to diversion of opioid pills. 1 2 that correct? 3 Α. Are you referring to a specific sentence or opinion? 4 I was -- I -- let me ask you -- it's the 5 last sentence under -- before heading C on page 22. 6 Α. Okay. And there's a reference to "causal" 8 9 relationship between prescription opioid exposure and opioid use disorder." Do you see that? 10 11 Α. Yes. 12 Ο. That's what I wanted to ask you about. So 13 when you use the phrase "exposure" there, are you talking about exposure of the community to opioid 14 15 pills? 16 MR. ARBITBLIT: Objection. 17 Α. Can you describe what you mean by 18 "community exposure?" 19 Well, maybe I should put it the other way What do you mean when you say 20 around. 21 "prescription opioid exposure"? I am referring to individuals who use 22 23 prescription opioids. So that means -- that means people who had 24 Q.

access to opioids once they were in the community?

MR. ARBITBLIT: Objection.

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- A. I don't think I mean anything other than people who take opioids.
- Q. Okay. And so when you use the phrase "exposure" there, you're referring to pills that have been dispensed into the marketplace and that are available for use?
 - A. No. I mean people who consume opioids.
- Q. Okay. And so your point is that people who consume opioids, some number of them engage in misuse of opioids? Is that right?

MR. ARBITBLIT: Objection.

A. I mean that when people consume opioids, there is a risk of opioid use disorder.

And opioid use disorder can include misuse.

- Q. So opioid use disorder can include both misuse or use pursuant to a doctor's prescription? Is that right?
- A. It depends on which definition in -- which definition of opioid use disorder we're -- what we're referring to.
 - Q. And could you just explain what you mean by

that point, which definition of opioid use disorder we're referring to?

A. In DSM-V, there was a change in the definition to -- to exclude opioid use disorder diagnoses based on tolerance and withdrawal as sole criteria for diagnosis.

So based on DSM-V, those people would -- who presumably could be medical users of opioids would be excluded from the diagnosis.

- Q. So let me ask you to look at page 6 of your report, please. And I wanted to ask you about Point 5 on this page.
 - A. Okay.

- Q. Where you say and it's the first sentence of that Point 5 "The expansion of non-medical prescription opioid use would not have occurred without the widespread availability of prescription opioids." You see that?
 - A. Yes.
- Q. And so is the point you're making there that nonmedical use of prescription opioids was expanded because prescription opioids were more widely available in the community?
 - A. I think the point that I'm making there is

that the expansion of nonmedical prescription opioid use occurred in part due to the widespread availability based on opioids that were originally dispensed for supposedly medical uses.

So I think the statement you made is a little broader than what the opinion is.

- Q. And is your opinion that there was an oversupply that was diverted to opioid misuse?
 - A. Yes.

- Q. And so the diversion you're describing is pills that made their way into the community and led to misuse; is that right?
- A. I would just refer to my definition of diversion that I'm using in the report for specificity, and so my definition of "diversion" includes the transfer of opioids obtained through legal medical sources to the illicit marketplace overall.

So I think it's a bit broader than your definition here, which is "pills that made their way into the community and led to misuse." That's more limited.

Q. But the pills that made their way into the community and led to misuse, in your view, are

Page 109 often diverted from a medical use to a nonmedical 1 2 use? 3 Α. They can be diverted. And so --Ο. 4 I would --5 Α. -- at page -- sorry. Sorry. 6 Q. 7 No, I'm finished with my answer. Α. At page 7, if you look at page 7 of your 8 Ο. 9 report, Point 12, and it's the last sentence of that point, you say, "The driving force in 10 increasing opioid-related morbidity and mortality 11 12 was, and continues to be, access to and wide-spread 13 availability to opioids." Is that right? Do you see that? 14 15 Α. I do. 16 0. So access means access to people in the 17 community after pills have left a pharmacy. 18 that right? 19 Not necessarily. 20 How does -- how does the community get Ο. 21 access to the pills? Through a physician, for example. 22 Α. 23 How else would the community have access to Q. 24 pills?

- A. I'm sorry, I'm -- I don't think I'm understanding the question. Is the question, what are all the sources of opioids?
- Q. No. Well, I guess what I'm -- what I'm trying to get to is this: When you're talking about access, you're talking about access to pills after they leave pharmacies. Is that right?
 - A. That's one source of opioids.

- Q. And what are other sources of opioids that get into the community and create this access you're describing?
- A. I think in my report, I review data specific to that topic and a modal source, for example, is obtaining opioid medications from family, for example. You know, there's a leftover bottle in the medicine cabinet because too many opioids were prescribed and someone gets access to them through their parents' medicine cabinet. That would be one example.
- Q. And so that example, after too many opioids were prescribed and somebody obtains them from the medicine cabinet, that would be after the pills left the pharmacy?
 - A. That would be after the pills left the

Page 111 pharmacy. 1 2 Ο. Your focus is on diversion of pills after 3 they leave the pharmacy. Is that correct? I don't know that I would make that blanket 4 5 statement. Do you have any evidence of diversion 6 Ο. 7 between the time that pills are shipped by distributors and they're delivered to pharmacies? 8 9 I don't -- I don't have -- I don't offer a 10 specific opinion on that topic. That could be the 11 case. The diversion you discuss is diversion of 12 Ο. pills after they have left pharmacies. Is that 1.3 right? 14 15 MR. ARBITBLIT: Objection. 16 Α. The diversion that I discuss is any 17 transfer of opioids to the illicit marketplace. 18 Ο. And that -- that's after they've left the 19 pharmacy? 20 MR. ARBITBLIT: Objection. 21 It could be after they leave the pharmacy. I'm not -- I'm not exclusively limiting my opinion 22 to -- on the harms of opioids to opioids that leave 23 24 the pharmacy.

- Q. There could also be opioids there illegally trafficked into a community?
 - A. Sure. Yes.

- Q. That never leave the pharmacy at all, right?
 - A. That's possible.
 - Q. But what I wanted to be clear on is:
 You're not offering an opinion on diversion of
 pills between the time a distributor ships them and
 delivers them to a pharmacy, are you?
 - A. My definition of "diversion" would include that type of activity.
 - Q. Do you have any evidence of that occurring in Cabell/Huntington?
 - A. I -- my report focuses on opioid-related harms overall. I don't offer an opinion on any specific -- any specific -- what is it? Illegal shipments of opioids.
 - Q. And you're not offering any opinions on the diversion of shipments between the time they leave a distributor's warehouse and the time they arrive at a pharmacy?
 - A. My opinion on diversion would be inclusive of that type of activity.

Q. But you don't have any evidence of that activity occurring, do you, in Cabell/Huntington?

A. I think my report offers evidence about overall sources of opioids that would be inclusive of any illegal -- any way that opioids are illegally-obtained.

I don't offer any opinions or have evidence about specific illegal shipments. But to the extent that that occurs, that would be included in my report on harms.

Q. Right. But I wanted to just be clear that
-- and I think we're talking the same language
here. I want to be clear that you're not
identifying any sources of diversion in relation to
shipments between distributors and pharmacies?

You haven't identified any such evidence?

A. Right.

Q. And when you talk about -- let's look at your report, page 27. And I wanted to point you to the last paragraph before Subpart E. And you refer to "a surplus of opioids that could be diverted for nonmedical uses." Do you see that? Sort of in the middle of that paragraph.

A. I do.

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- Q. And that's a -- that's a surplus that is in the community after it's left the -- after it's left pharmacies; is that right?
 - A. Not necessarily.
- Q. Are you aware of any surplus that's created except after the pills leave pharmacies?
- A. I'm not identifying any particular shipments. But any -- any surplus that occurred in the community would be a surplus regardless of where the surplus originated.
- Q. I believe you've expressed the opinion in your report that diversion between family and friends is the most common pathway for diversion.

 Is that right?
 - A. It is a common pathway.
- Q. And do you agree that distributors do not have a way to prevent family members from sharing pills once they receive them?
- A. I wouldn't agree with that as a blanket statement.
- Q. How would distributors prevent family members from sharing pills once they receive them?
 - A. I can't identify any particular ways of --

Page 115 that distributors would do that, but I -- I'm not 1 2 aware -- I don't offer an opinion either way. 3 just wouldn't make the blanket statement that distributors can and cannot prevent any activity. 5 You understand that prescription opioids can't leave a pharmacy unless the doctor writes a 6 7 prescription? There are other ways that opioids could 8 9 leave a pharmacy. Are you thinking of theft from the 10 11 pharmacy? 12 Α. For example. 13 What other ways? Q. Other sources of diversion, you know, 14 15 selling, illegal selling, for example. So I -- just to be clear, the -- when pills 16 Q. 17 are at a pharmacy, one way pills leave the pharmacy 18 and reach the community is through prescriptions written by doctors, right? 19 20 Α. That's correct. 21 Ο. Another way is if pills were sold illegally 22 out of a pharmacy; is that right? 23 Α. That is another way, yes. 24 And another way would be theft from Q.

Page 116 pharmacies? 1 Α. That's another way. 3 Ο. Are there others that occur to you that -ways that pills leave pharmacies and get into the community? 5 Α. None come to mind. 6 7 Ο. And do you have any evidence of any theft from pharmacies occurring in Cabell/Huntington? 8 9 I haven't reviewed that type of data for 10 this report. 11 And do you have any evidence of pills being 0. 12 sold illegally from pharmacies in 13 Cabell/Huntington? Again, I'm -- I haven't reviewed that 14 15 evidence. You agree that -- that doctors decide on 16 Ο. 17 the prescriptions that they believe are warranted 18 for the treatment of pain? I wouldn't make that as a blanket 19 20 statement. 21 Ο. Do you have an understanding that when a doctor writes a prescription for a medical purpose 22 23 for prescription opioids, the doctor's exercising 24 his or her judgment that the medical use is

Page 117 warranted? 1 2 MR. ARBITBLIT: Objection. 3 Α. The doctor's judgment is based on the information that's available. So in some cases, 4 5 the doctor is using their -- the judgment that they have based on potentially misleading information, 6 7 and also there are doctors that prescribe with no medical purpose at all. 8 9 So for -- but for doctors who are 10 prescribing for medical purpose, they're making a judgment that the prescription opioids are 11 warranted for that purpose. That's your 12 13 understanding? 14 MR. ARBITBLIT: Objection. 15 I wouldn't say that's a -- that's true across the board. It can be true, but I wouldn't 16 17 say that that's always true. 18 They -- you think that doctors are not Ο. making medical judgments when they write a 19 prescription for opioids? 20 21 MR. ARBITBLIT: Objection. I think some doctors prescribe with --22 Α. 23 without medical judgment, and I think the opinion 24 that I'm offering is that -- I think that's the

Page 118 opinion that I'm offering, that there are -- I 1 2 wouldn't make a blanket statement about all types 3 of judgments that physicians use when they're prescribing opioids. 4 5 Those judgments are oftentimes based on misleading information. 6 7 I was -- I was trying to separate the information that the doctor has from the good faith 8 9 judgment that the doctor is making. Is it your 10 understanding that when a doctor writes a 11 prescription, the doctor is undertaking to make a 12 good faith judgment that the prescription is 13 warranted? MR. ARBITBLIT: Objection. 14 15 Some doctors are; and some are not. So I can't make a blanket statement about that. 16 17 Ο. Do you know the percentage of doctors that 18 are or are not making a good faith judgment when they write prescriptions? 19 20 Yes, there's a section in my report on that Α. 21 topic. Can you easily find that? 22 Ο. Where? 23 Α. Section C. 24 What page are you on? Q.

A. Page 24. I think there's a couple different data sources that I would use to inform an opinion about that. One is that among people with OUD, more than 50 percent obtain prescriptions from a doctor.

And second, there are numerous data sources on multiple providers that could be recklessly prescribing, and there's data on prevalence of that. So I would point to those papers.

- Q. So that the people with OUD who obtain prescriptions from doctors, those are not necessarily people who are receiving a prescription written by a doctor in bad faith, are they?

 MR. ARBITBLIT: Objection.
 - A. Not necessarily.
- Q. But in any event, the pills can't leave the pharmacy under a prescription unless the doctor writes one. Correct?
- A. Again, I don't -- I don't think I would make that blanket statement. There could be other ways that people with a prescription could obtain opioids. One way is someone has a prescription and they walk into a pharmacy and they fill it. There

are other ways as well.

- Q. Do you understand that distributors shipped the volumes of prescription opioids that were needed to meet the levels that doctors prescribed?

 MR. ARBITBLIT: Objection.
- A. I wouldn't make that blanket statement. I wouldn't agree with that statement as a blanket statement.
- Q. Do you -- do you have any evidence that distributors shipped more than what doctors prescribed?
- A. I'm not offering an opinion on specific shipments. I know the overall amount that was shipped was more than was needed.
- Q. No, I'm not asking about what was needed.

 I'm asking about whether doctors -- I'm sorry.

 MR. HESTER: Let me strike that.
- Q. I'm asking whether distributors shipped more than what doctors prescribed. Do you have an understanding that distributors only shipped what
- A. I have an understanding generally of -- of the distribution process, but I'm not offering an opinion about -- about the relationship between

doctors prescribed?

prescription and distribution specifically.

- Q. Okay. At the -- at the --
- MR. HESTER: Let me strike -- sorry.
- 4 Let me strike that.
- Q. Let's turn to page 6 of your report,
- 6 | please. And it -- I wanted to point you to
- 7 Paragraph 5. You refer to a "widespread
- 8 availability of prescription opioids that were
- 9 originally dispensed supposedly" "for medical uses,
- 10 uses, often in greater quantities and doses than
- 11 needed."

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- Do you see that?
- A. Well, just to quote it accurately, it's
- 14 | "originally dispensed supposedly (but not always
- 15 | actually) for medical uses." Just to --
- 16 Q. Fair enough. Fair enough. I omitted that
- 17 because I didn't want to ask you about that part; I
- 18 | wanted to ask you about another part, which was:
- 19 | How do you decide on what is a surplus or an
- 20 oversupply?
- 21 A. My opinion about that was based on the
- 22 | epidemiological literature that indicated that
- 23 | there's often more opioids dispensed than are
- 24 medically needed.

- Q. And that's dispensed from pharmacies?
- A. Again, that's one source of oversupply.
- Q. But when you say -- when you say "more opioids dispensed than what is needed," you're saying more opioids dispensed from pharmacies than was needed?
- 7 A. That specific clause refers to that -- that 8 realm.
 - O. And --

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- 10 A. But there are others.
- Q. Sorry. And the -- what methodology you're

 -- is applicable there? You're relying on

 epidemiological studies on that?
 - A. That's correct.
 - Q. And can you -- can you point me to where you're doing that in your report? I think maybe it could be at page 23. See if we get to the right place.
 - A. Yes, that's correct.
 - Q. And so what are the -- what are the epidemiological studies that you're referring to there?
- A. So for example, "Available estimates indicate that 90% of patients prescribed opioids

after a surgery have unused medication." That would are one -- and there are three studies supporting that.

- Q. So that would be -- that would be an example where a doctor prescribed prescription opioids and there were unused opioids left after the course of treatment? Is that right?
 - A. That's right.
- Q. And is there anything else you're relying on aside from those epidemiological studies to make a conclusion about what was a surplus or an oversupply?
 - A. Yes.

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- Q. What else?
- A. So the next study that is described in this section is on nonmedical opioid users being interviewed about where they obtained opioids. For example, 50% "received from a friend or a relative." That's not necessarily a pharmacy source, but could be.

And then the next section is peers or family, the most common source of opioids for college students, and there's two studies cited there.

And again, that's not necessarily a pharmacy source. But it could be.

Then the next one is a study that showed that opioid dispensing to family members is associated with three times the risk of a prospective individual hospitalized overdose. And so those presumably would be pharmacy sources.

And then the next section goes into detail about individuals receiving opioids from multiple prescribers and high-volume prescribers.

- Q. So -- okay. So when you're saying that there's a surplus or an oversupply, do you base that on the fact that there's excess medication that family and friends have available to divert to others? Is that the basis on which you characterize it as an oversupply?
 - A. That's one source of oversupply.
- Q. I'm trying to get at the question of how you conclude it's an oversupply. How do you -- how do you decide that it's an oversupply?
- A. So based on the totality of the literature, that there is a lot of excess opioids that were not used medical -- not needed medically. So that includes --

Q. And --

- A. -- family, friends. That includes prescriptions. That includes other sources of diversion.
- Q. Have you evaluated the medical needs for prescription opioids in West Virginia?
- A. Can you say what you mean by "medical needs"?
- Q. Well, do you agree that there are legitimate medical needs for opioids?

 MR. ARBITBLIT: Objection.
- A. I think that -- sure, there are -- there are uses for opioids, and there are uses for opioids in the Cabell/Huntington community. But I think what the evidence shows is that there was -- the distribution of opioids into the Cabell/Huntington community is clearly well over what is needed.
- Q. But let me -- let me then just drill into that question. Have you undertaken any study to evaluate what level of opioids are needed in the Cabell/Huntington community?
- A. There is literature on -- on guidance regarding opioid prescribing that is relatively up

Page 126 to date, and so I would rely on that quidance to 1 2 answer that question. 3 I have not applied current high rigor quidance specifically to the Cabell/Huntington community. 5 So you've not undertaken any evaluation of 6 Q. 7 how many pills are needed in Cabell/Huntington? MR. ARBITBLIT: Objection. 8 9 I -- no, I have not taken -- I've not 10 undertaken that. 11 And the guidance you referred to, is that Ο. the CDC guidance on prescription opioid 12 prescribing? 13 That's one source. 14 15 Ο. What other guidance are you referring to? There's been a number of other quidance 16 Α. 17 sources that I cited in the report. Okay. So I may circle back to that. 18 Ο. You're not an expert in pain management, I take it? 19 20 MR. ARBITBLIT: Objection. 21 I think part of having epidemiological expertise on opioid use disorder is a general 22 23 knowledge of that literature.

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But you don't treat patients for pain?

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Q.

A. I don't treat patients for pain.

- Q. And have you evaluated the medical need for opioids in West Virginia?
- A. I've generally evaluated medical needs for opioids, and I would say that those findings generalize to West Virginia.
- Q. And what have you done to evaluate the medical needs for opioids?
 - A. I've reviewed literature.
- Q. What literature have you seen evaluating the medical needs for opioids?
- A. I think there's a number of studies that have discussed appropriate uses of opioids.
- Q. Yeah, but I'm talking about -- well, maybe let's back up to make sure we're on the same page. The overall supply of opioids in the community reflects an aggregation of judgments by doctors about what's medically needed, right?

MR. ARBITBLIT: Objection.

- A. I wouldn't make that blanket statement.
- Q. Well, let's focus on prescriptions written by doctors for legitimate medical need. The prescriptions written by doctors for medical -- for legitimate medical need, those would aggregated to

Page 128 a judgment by doctors about the medical need. 1 2 Correct? 3 MR. ARBITBLIT: Objection. Α. I don't think that most doctors -4 5 especially during this time period - had sufficient guidance on what is a legitimate medical need in 6 7 order to suggest that -- that the entire supply of opioids to the Cabell/Huntington community that is 8 9 written by doctors would be based on legitimate medical need. 10 But doctors make that judgment about what's 11 Ο. needed? 12 13 MR. ARBITBLIT: Objection. Do doctors make a judgment about what's 14 15 needed? I think some doctors make judgments in 16 good faith; other doctors do not. 17 But for those judgments who make -- I'm Ο. 18 sorry. MR. HESTER: Strike that. 19 20 For those doctors who make judgments in Ο. 21 good faith, they're making judgments about what they believe is medically needed. Right? 22 23 MR. ARBITBLIT: Objection. 24 They are making judgments based on a set of Α.

evidence that might be tainted by not sufficient rigor. They might not be up to date on current trainings. I mean, to suggest that all doctors were writing prescriptions in good faith or making medically-legitimate decisions, I think would be a mischaracterization of what we've seen in the opioid epidemic.

- Q. You have not evaluated, though, what the level of medical need is in West Virginia?
- MR. ARBITBLIT: Objection, asked and answered.
 - A. I have evaluated literature about medical uses of opioids and I believe that those findings are generalized to West Virginia.
 - Q. I think there's a difference though. Your answer referred to medical uses. I'm talking about the aggregate medical need, and what I wanted to ask you about is -- is any literature dealing with the aggregate medical need for opioids. Have you evaluated that question?

MR. ARBITBLIT: Objection.

A. No.

Q. When you refer to quantities and doses at page 6 of your report, you refer to "prescription"

Page 130 opioids that were" "dispensed" "in greater 1 2 quantities and doses than needed." Do you see 3 It's again on -- that Point 5 on page 6. Α. 4 Yes. The doctors are the ones who decide on a 5 quantity and dose for a given prescription, right? 6 7 MR. ARBITBLIT: Objection. Α. In this specific context. In this specific 8 9 opinion. I'm specifically referring to "dispensed" opioids in "quantities and doses greater than 10 11 needed." And in that case, the physician would be 12 writing a prescription, in most cases. Although 13 not necessarily all. But the prescription -- the prescription 14 with the quantity and the dose, that's something 15 that the doctor decides on? 16 17 MR. ARBITBLIT: Objection. When there is a prescription written by a 18 Α. 19 doctor. 20 And the distributors don't decide on the Ο. 21 quantity and dose for particular prescriptions, right? 22 23 Distributors don't write prescriptions,

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that's correct.

- Q. Do you agree or understand that the expansion of nonmedical use of prescription opioids would not have occurred without the increase in supply caused by doctors' prescriptions?
- A. I agree that that is one source of the increase in supply.
- Q. And we've talked about some of the other sources of increased supply as well, right?
 - A. We've talked about some of them.
- Q. What are -- what are the other sources you have in mind, aside from doctor prescribing? What are the other sources for increases in supply?
- A. Your question is: What are the sources of prescription opioid supply?
- Q. Yes. You said one source is doctors' prescriptions. What are other sources?
- A. I think the amount of product that is made and distributed in the United States that could be diverted at any point along the chain from the making of the product to it arriving in a community.
- Q. Well, let's -- maybe let's focus more specifically so we don't make it too cosmic. Let's focus specifically on Huntington/Cabell. I take it

you do have evidence of prescribing behavior in Huntington/Cabell that led to an increase in supply of prescription opioids?

MR. ARBITBLIT: Object to form.

- A. I have evidence of the distribution of prescription opioids in the Cabell/Huntington community.
- Q. You have evidence of an increase in supply that was caused by doctor prescribing behavior, correct?
- A. I have evidence of the distribution. Some of that could have arrived -- become disseminated into the community through a prescription, and there might be other sources as well.
- Q. Well, that's what I want to focus on, ways, to your understand, that prescription opioids were disseminated into the Huntington/Cabell community.

 One way, I take it, is by prescriptions written by doctors. Right?
 - A. Yes.

- Q. What other ways are you aware of that prescription -- that prescription opioid supply increased in Huntington/Cabell into the community?
 - A. I don't -- I think I've answered the

question. I'm not sure -- what are other ways that
-- so you're asking one way that prescription
opioids be -- get into a community is because a
doctor writes a prescription for them?

Q. Right.

A. Other ways are through other sources of diversion that we've mentioned: You know, family, friend, peer, drug dealer, you know, anyone who has access to opioids through the way that they access them.

Maybe through informal social networks of sharing medication. Maybe it was through counterfeit medication. I mean, there's other ways that prescription opioids can be in a community.

Q. The -- but your view is that the expansion of nonmedical use would not have occurred without an increase in the supply of prescription opioids in the community?

MR. ARBITBLIT: Objection.

- A. That's correct.
- Q. Have you performed any analysis as to whether the opioid crisis would have occurred or occurred in the same way if doctors had not increased their prescribing of prescription

Page 134 opioids? 1 2 MR. ARBITBLIT: Asked and answered. 3 Α. Yes, I think there is literature on that topic, that doctors writing prescriptions is one 4 5 way that contributed to the opioid crisis. Yeah, I was asking really the other side of 6 7 it. I was asking, have you done an analysis as to whether the opioid epidemic would have occurred in 8 9 the same way if doctors had not increased their level of prescribing? 10 11 MR. ARBITBLIT: Objection. 12 Α. I think that it would not have occurred in 13 the same way if doctors had not increased their prescribing, based on the studies that were done. 14 15 So I think my analysis is the review of the literature, and I think the opioid epidemic would 16 17 not have occurred in the same way if doctors had 18 not increased their level of prescribing. 19 We talked a minute ago about the prescribing beyond recommended guidelines, and let 20 21 me point you to Exhibit 4. I don't think we've 22 opened that up yet. KEYES DEPOSITION EXHIBIT NO. 4 2.3

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(CDC Guideline for Prescribing Opioids

Page 135 for Chronic Pain - United States, 2016 1 2 was marked for identification purposes 3 as Keyes Deposition Exhibit No. 4.) 4 Q. Do you have that one there? 5 Α. I do. So Exhibit 4 is the CDC Guideline for 6 Ο. 7 Prescribing Opioids for Chronic Pain - United States, 2016. 8 9 Are these the quidelines you are 10 referring to when you said you saw evidence of prescribing beyond quidelines? 11 One set of guidelines. There are --12 Α. There are -- sorry. Are there others you 13 Ο. had in mind? 14 15 I believe there are several others that are 16 cited in my report. 17 Ο. Can you point me to those? I couldn't figure out when I saw a reference to guidelines, I 18 wasn't sure what you were referring to. 19 20 I'm sorry, I'm just looking through my 21 reference list. I believe that there are other 22 guidelines that have been published, for example, 23 by NIDA. 24 Q. Are those cited in your report?

- A. I think so, but I could double-check.
- Q. Any other quidelines that you had in mind?
- A. I believe that the Association of Schools and Programs of Public Health published in 2019 also has prescribing guidelines in it. That's Reference 45.
- Q. Okay. Thank you. Let's just look at the CDC Guidelines for a minute, Exhibit 4. Is it your understanding that these guidelines are not meant to prevent physicians from prescribing in excess of the guidelines?

MR. ARBITBLIT: Objection.

- A. Can you rephrase? I don't think I understand the question.
- Q. Do you have an understanding that these guidelines were intended to set recommendations but not to prevent prescribing in excess of the guidelines?

MR. ARBITBLIT: Objection.

- A. My understanding is that these guidelines do not prevent prescribing in excess of them.
- Q. And that's reflected -- I -- I'm not trying to play a game with you on that. I think that's reflected but let me see if you agree on page

2. The -- in the right-hand column of page 2, before Rationale, there's a statement three sentences up. It says, "The recommendations in the guideline are voluntary, rather than prescriptive standards."

Do you see that?

A. I see that.

- Q. And so that reflects the point that these were meant to be voluntary -- voluntary recommendations and not to prevent doctors from prescribing in excess when they believe that was medically warranted?
- A. I think the guidelines do not prevent people from prescribing excessive amounts of opioids.
- Q. And it was left to doctors to decide on the risks and the benefits of what they would prescribe?

MR. ARBITBLIT: Objection.

A. I think -- I think the guidelines don't prevent doctors from prescribing levels of opioids beyond that which is recommended. Whether they're prescribing those above the level that are recommended, what are -- what is driving those

Page 138 decisions, I'm -- I don't think risks and benefits 1 2 are among the only factors. 3 Q. Correct. They also have to take into account the information they've been given. 5 And -- but those -- those risks and 6 7 benefits are weighed by doctors and not distributors. Correct? 8 9 MR. ARBITBLIT: Objection. I think that a doctor's knowledge of the 10 11 risks and benefits are based on the information 12 that they've been given. I don't think 13 distributors prescribe opioids. But I don't think it would be accurate to say that the distributors 14 15 don't have a role here. The doctors formulate their judgments about 16 Ο. the risks and benefits of medicines based on a wide 17 18 range of inputs. Do you agree? 19 MR. ARBITBLIT: Objection. 20 It would depend on the medication. I Α. 21 wouldn't make a blanket statement. Do you understand that doctors form 22 Ο.

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judgments about particular -- prescribing of

particular medicines based on their clinical

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Page 139
experience with other patients?

A. I think that can be one source of information, among others.

- Q. Another source would be whatever they're taught in medical school?
- A. Again, I think that can be a source of information, and it would depend on how the information that's being taught in medical school was derived. Not derived de novo, as I've testified before.
- Q. Let me ask you to look at your report, page 22. At the bottom of the page, the very last sentence, you refer to "pervasive oversupply from high volume facilities."

Do you see that?

- A. I do. "...facilities and pharmacies distributing extraordinary quantities of opioids."
- Q. Right, right, okay, good. What do you mean there by "high volume"?
- A. That has been defined in the literature.

 Let's see. I just want to make sure that I'm

 giving the correct -- I think I would need to go to

 these specific studies to know exactly how most of

 the literature defines it.

I mean, generally it's a very high quantity of opioids. But the specific number that's used, I would need to look at the studies again to know that for sure.

- Q. What's the basis for your knowledge about high volume facilities? Is it based on a review of the literature?
- A. Yes.
- Q. Have you done any independent study yourself of what a high volume facility is?
- 11 A. No.

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- MR. ARBITBLIT: Objection.
- A. I've reviewed the literature. That -- the analysis that I've done is a review of the literature.
 - Q. Have you evaluated any high volume facilities in Cabell/Huntington?
 - A. Yes. That's included in here through the IQVIA data in terms of what's been published in the literature.
 - Q. Do you know what page you're on when you refer to that?
- A. 25. I'm fairly clear that -- I'm fairly certain that those rates have been published.

Q. So I see on page 25, you're referring to prescribers with a high volume or extraordinary volume of prescriptions. I was asking about high volume facilities.

Do you -- is that synonymous for you, or is it -- is there a difference between a high volume facility and a high volume prescriber?

- A. Those would be the -- it depends. They can be similar; they can be different.
 - Q. So if a high volume --
 - A. The literature --
- Q. Sorry.

- A. -- when they talk about high volume providers, those are often referred to as pill mills, and so within a specific high volume facility, there might be -- the high volume facility would be made up of high volume prescribers.
- Q. But a high volume facility -- just to make sure we're talking the same language, a high volume facility could include a pain clinic?
 - MR. ARBITBLIT: Objection.
- Q. Is that one of the ways -- one of the types of facilities you might consider a high volume

Page 142 facility? 1 2 MR. ARBITBLIT: Objection. 3 Α. Sorry, let me just look at the -- what do you mean by a "pain clinic?" Well, do you know what pain clinics are? 5 Ο. MR. ARBITBLIT: Objection. 6 7 In other words, a clinic that is Ο. specifically focused on treating pain. Are you 8 aware of those? 9 I'm aware that there are clinics that focus 10 on -- on -- that supposedly focus on the treatment 11 12 of pain. 13 O. And --14 -- under many conditions. 15 Ο. Sorry. I didn't mean to interrupt you. Have you evaluated any pain clinics in 16 17 Cabell/Huntington? 18 MR. ARBITBLIT: Objection. I've evaluated the overall distribution of 19 20 opioids. I don't know that I would -- I haven't 21 evaluated any specific clinics. 22 I've looked at high volume prescribers 23 and high volume prescribing. 24 Q. You're aware that doctors today are still

prescribing in West Virginia a meaningful volume of prescription opioids, right?

A. Yes.

Q. And to -- do you have an understanding as to whether doctors in West Virginia today have been apprised of the addiction risks of prescription opioids?

MR. ARBITBLIT: Objection.

- A. I don't know what any one particular doctor has been informed of.
- Q. Do you believe the population of doctors in West Virginia have been informed of the addiction risks associated with opioids?

MR. ARBITBLIT: Objection.

- A. I don't have any data on that topic.
- Q. So you don't have an understanding one way or the other as to whether doctors in West Virginia have been apprised of the addiction risks of opioids?
 - A. That's correct.
- Q. Have you undertaken any evaluation of the standard of care for treating pain?
- A. I have reviewed guidelines that have been published in the literature on pain.

- Q. Is that the CDC guidelines or other things you're thinking of?
- A. The same documents that I had mentioned in our previous conversation.
 - Q. Okay.

- A. Well, there's other literature as well cited in the report about pain treatment efficacy.
- Q. And have you undertaken any analysis of pain needs specifically in Cabell/Huntington community?
- MR. ARBITBLIT: Objection. Asked and answered.
- A. No.
 - Q. And have you undertaken any specific evaluation of pain needs in West Virginia?
 - A. I would only say to the extent that, you know, the available literature has characterized overall levels of pain that I would say generalized to that area. But beyond review of the general literature, I have not done any specific analysis of West Virginia.
 - Q. And is the literature you're thinking of literature that evaluates the standard of pain in West Virginia, or is it really more nationwide?

- A. I would say that it's more general.
- Q. And have you seen any studies reflecting that there may be higher pain needs in West Virginia?
 - A. I seen some literature on that.
- Q. And do you have an understanding that one of the factors that may lead to higher needs for pain treatment in West Virginia is the nature of the physical work engaged in in the state?
 - A. Yes, I've seen literature on that.
- Q. And do you have an understanding as well that the higher levels of obesity in West Virginia may be another factor that leads to higher needs for pain treatment in the state?
 - A. That -- that could lead to pain, yes.
- Q. And you've seen studies or documents to that effect?
 - A. Generally, yes.

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- Q. Are -- we've talked about obesity and physical labor. Are there other factors you've seen that are specific to West Virginia that may lead to higher needs for pain treatment?
- A. I would need to review the literature again. Nothing comes to mind.

- Q. Nothing comes to mind?
- A. (Nodded affirmatively).

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- Q. Have you evaluated the changes in the standard of care for the treatment of pain?
- A. I'm generally familiar with the fact that there have been changes. But I didn't -- I didn't review that literature in order to form opinions of it. I'm just generally aware of it.
- Q. And what's your general understanding of the changes in the standard of care for the treatment of pain?
- A. I think the most recent changes, is that there has been widespread recognition that opioid prescribing has too many risks and too many benefits to be -- to be of use in widespread treatment of pain.
- Q. You're talking there about chronic pain or acute pain?
 - A. I think both.
- Q. Do you believe that opioids are widely used for the treatment of acute pain?
- A. I think that there is literature to that effect.
 - Q. I wanted to focus really on -- on the

Page 147 treatment of pain as a concept. You're aware that 1 2 there have been changes in the standard for the 3 treatment of pain. MR. ARBITBLIT: Objection. 4 5 I quess I'm not sure what you mean by "pain as a concept." 6 Well, you understand there's a -- there's a focus on the need to enhance the treatment of pain. 8 9 This has been a focus in the medical community? 10 MR. ARBITBLIT: Objection. 11 I think that there -- I have seen 12 literature on -- for example, pain as the fifth 13 vital sign, that is largely industry-supported. So to the extent that there is a general feeling in 14 15 the medical community that hasn't been influenced 16 by industry, I'm not sure about that. 17 And certainly not in recent years. 18 So you don't have -- beyond what you just said, do you have any further information or 19 understanding on the changes in standard of care 20 21 for the treatment of pain? 22 MR. ARBITBLIT: Objection. 23 I -- if you have specific questions, I 24 could answer them. But in terms of general

understanding, I'm generally familiar about that there have been changes.

- Q. Have you evaluated any statements that were made by the state of West Virginia government about the use of opioids for the treatment of pain?
 - A. No.

Oh, actually, I have reviewed. I think in the course of writing my report, I have reviewed State Department of Health and other governmental body reports, and some of those might have had statements.

And so I might have reviewed some of that material.

- Q. Is that -- is that something you factored into your opinions, the statements made by the West Virginia government on the use of opioids in the treatment of pain?
- A. I factored it in. I evaluated it, the materials that I reviewed.
- Q. So when you speak about appropriate levels of prescription opioids in West Virginia, have you evaluated the standards of care in making those statements?
 - A. I have evaluated the general literature on

opioid risks and benefits when forming my opinions.

And so if you have a specific standard of care in mind, I could see how it comports with my opinions.

Q. Do you have an understanding that there was an increase in the desire to treat pain in this country?

MR. ARBITBLIT: Objection.

- A. I would say that's a little bit too vague for me to agree or disagree with.
- Q. The -- how did the standard of care for the treatment of pain factor into your evaluation of the excess supply of prescription opioids?
- A. I would say in general, I evaluated -- as I said, I evaluated the literature, the medical literature, on risks and benefits when forming my opinion.

And so -- and so that's what formed my opinion. Rather than any particular standard.

- Q. Let me ask you -- I know you were questioned previously in other depositions about the DEA annual production quotas. Do you remember that?
 - A. I do.
 - Q. And is it your understanding that the

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quotas set by the DEA apply to the supply of opioids in West Virginia?

A. Yes.

- Q. And is it your understanding that the supply of opioids in West Virginia was within the quotas set by DEA?
 - A. I haven't evaluated that.
- Q. Do you have any knowledge one way or the other as to whether the pills distributed by the distributors in West Virginia were within the DEA quotas?
- A. I have not evaluated the DEA quotas for West Virginia, so I don't have an opinion on that.
- Q. Do you know anything about the information that distributors reported to the DEA about their distribution of prescription opioids in West Virginia?
- A. I have not evaluated any communication with the DEA.
- Q. And do you know anything about the information the distributors reported to State regulators about their distribution of prescription opioids in West Virginia?
 - A. I have not evaluated that information.

- Q. And do you know anything about the systems any of the distributors had in place to prevent diversion of prescription opioids in West Virginia?

 MR. ARBITBLIT: Objection.
- A. I've seen some literature on that -- on that topic.
 - Q. Is that part of your opinions in this case?

 MR. ARBITBLIT: Objection.
- A. I have not -- I have not formed any opinions in the report on that, but if asked about that, you know, I do know something about it. So that was -- that was forming my answer to your question.
 - Q. Okay.

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- MR. HESTER: Let's go off the record a second, if we could.
- VIDEO OPERATOR: Going off the record.

 The time is 12:22 p.m.

(A discussion was had off the record after which the proceedings continued as follows:)

VIDEO OPERATOR: Now begins Media Unit 4 in the deposition of Katherine Keyes. We're back on the record. The time is 12:23 p.m.

Page 152 BY MR. HESTER: 1 2 Doctor Keyes, let me point you to twenty --Ο. 3 page 28 of your report, please. And on page 28, in the second full paragraph, starts "The empirical 5 literature demonstrates a strong and statistically significant association between the opioid supply 6 7 and increase in prescription opioid deaths." Do you see that? 8 9 Α. T do. And is -- is that a point that applies to 10 Ο. 11 prescription opioid deaths in West Virginia? Yes. 12 Α. When you say "association," what do you 13 Q. mean by that? 14 In this particular case, I think that the 15 16 increase in the supply caused an increase in 17 prescription opioid deaths. And that -- that cause was supply that led 18 to diversion that led to misuse that led to deaths? 19 Is that the sequence that you're -- that you're 20 21 referring to? 22 MR. ARBITBLIT: Objection.

A. That's one sequence. But there are also harms among people who took their medication as

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Page 153 prescribed. 1 2 Ο. Do you have any evidence of prescription 3 opioid deaths in West Virginia due to patients who are taking their prescriptions as prescribed? 4 Yes. I -- that's been documented in the 5 literature, and I have no reason to think it --6 7 that would not generalize to West Virginia. Prescription opioid deaths or misuse? 8 Ο. 9 Α. Deaths. 10 MR. ARBITBLIT: Objection. 11 What do -- what are you referring to in the Ο. literature on that? 12 13 There's a study by Bohnert, and there's two other studies, I believe, that they are in the 14 15 reference list. 16 Ο. The association that you refer to here is 17 the association between the opioid supply and the 18 increase in prescription opioid deaths, right? 19 Yes. But that's --Α. 20 And --Ο. 21 Are you asking me what's written? 22 Ο. Yes. And my question is this: Is the supply that you describe here, leads to misuse of 23 prescription opioids? Is that one of the factors 24

Page 154 you cite? 1 2 MR. ARBITBLIT: Objection, asked and 3 answered. Α. That is one, and there are others as well. 4 5 And is there empirical literature that demonstrates a strong and statistically-significant 6 7 association between opioid supply and the increase in prescription opioid deaths when opioids were 8 9 taken pursuant to a doctor's instructions? 10 Α. Yes. 11 And that's the Bohnert study that you referred to? 12 I believe there's three studies that have 13 evaluated that, Bohnert, and there's two others 14 15 that I couldn't find. And those are all cited in your report? 16 Ο. 17 Α. Yes. 18 When literature speaks about an association, that's -- that has a meaning that's 19 different from cause and effect. 20 21 MR. ARBITBLIT: Objection. Not necessarily. Not in all circumstances. 22 Α. 23 Ο. But in some circumstances, an association 24 is different from cause and effect. Right?

Page 155 MR. ARBITBLIT: Objection. 1 2 It would depend on the circumstance. There 3 are -- there are associations. Some of those associations are causal. 4 Let me ask you to look back at Exhibit 106, 5 please. 6 Which one is 106? Α. Oh, Exhibit 106, it's in your stack 8 9 already. It's your paper on the urban --10 Α. I see. -- versus rural divide. And I wanted to 11 Ο. 12 point you to E-54 of the paper, please. 13 there's a sentence in the middle column just before the "Outmigration of Young People" reference, and 14 15 it says, "A higher density of available opioids may create opportunities for illegal markets in rural 16 17 areas because family and friends are a primary 18 distribution source of nonmedical prescription 19 opioids." 20 Do you see that? 21 Α. Yes. 22 And is that point applicable to West Virginia, in your view? 23 24 Α. Yes.

- Q. And when you refer there to "illegal markets," what are you referring to?
- A. I would refer to, for example, drug selling. Selling an opioid to a friend for money.
 - Q. And why -- why -- well, maybe --
- MR. HESTER: Let me strike that.
 - Q. You refer there to "illegal markets in rural areas." So you're highlighting this as something that is particularly relevant to rural areas; is that right?
 - A. It occurs in urban areas as well. That statement is in the general context of describing the increase in prescription opioid harms in rural communities, but not every factor is specific to rural communities.

It's kind of considered as a whole.

- Q. But you called this out as something that you saw, illegal markets in rural areas, as something that you had seen?
 - A. In the literature. Yes.
- Q. You hadn't studied it yourself. You were looking at literature?
- MR. ARBITBLIT: Objection.
- 24 A. Let me --

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Q. That's probably not a fair question to an epidemiologist. I'll strike that.

The -- is there something about rural areas that creates unusual opportunities for illegal markets in prescription opioids to arise?

A. No.

Q. So -- so to discuss this a little bit more, this observation that you're making, when you say "a higher density of available opioids," is that a higher density of available opioids that arises out of prescribing by doctors?

MR. ARBITBLIT: Objection.

- A. I think that it would not be exclusive to prescribing by doctors. It would be availability through other sources as well.
- Q. And when you say "availability," you mean that the opioids are available in the community?
 - A. Yes.
- Q. And so what is the reference to "higher density of available opioids" mean? What is higher density?
- A. That would mean that per capita, there are more opioids available to an individual in these -- some of these rural areas, especially in West

Virginia.

- Q. And so -- and so that -- that per capita density of opioids created opportunities for misuse of opioids?
 - A. Yes.
- Q. And that misuse led to harm in some percentage of cases?
- A. In some percentage of cases. That's not the only source of harm, but it is one.
- Q. Is it analogous to saying that when there's a greater density of liquor stores on street corners, there's a higher incidence of alcoholism?
- A. I wouldn't say it's a one-to-one analogy.

 But in general, the kind of availability principle
 is that harms will arise when addictive substances
 are more available, however that availability comes
 to be.

One way could be through licensed alcohol outlets; and another way could be through bootleg alcohol that someone makes in their house.

Q. And in your report at page 12, you refer to addiction and related harms as multi-factorial. I can point you to the reference, but I may have it in your head. This kind -- I wanted to ask you

Page 159 about the phrase "multi-factorial." 1 2 Α. Sure. What does "multi-factorial" mean? 3 Ο. That generally refers to risk factors. 4 5 Risk factors generally in epidemiology are causal exposures that may be alone, insufficient and 6 7 alone, unnecessary to cause an outcome. So many health outcomes have multiple 8 9 risk factors. 10 And so in your report at page 21, you refer to "individual risk factors" in the second 11 12 paragraph. Right? 13 Α. Yes. And one -- one that you identify is a 14 15 lifetime history of psychoactive illicit drug use? That's right. 16 Α. And another one is lifetime psychiatric or 17 0. substance use disorder? 18 19 Α. Yes. 20 And so those are factors that are separate Ο. 21 from the supply of opioids that would be risk factors for OUD, correct? 22 23 MR. ARBITBLIT: Objection. 24 Α. I don't think they would be separate. We

would consider them together in sort of a multi-factorial framework.

- Q. But so when we talk --
- A. And --

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- Q. Sorry, go ahead.
- A. I was going to say, there's only one necessary factor for the opioid use disorder, which is the supply of opioids.
- Q. Because if you have no supply, you have no OUD, right?
- A. Yes. And so these other factors kind of potentiate the effect of that supply.
- Q. So the other factors that you're describing here interact or work together with the supply to create the OUD incidence?
- A. Or some individuals. But a real Hallmark of the risk factor framework is that none of these factors except the opioid supply are necessary, so you know, having an illicit drug use disorder certainly increases your risk of having problems with opioids, but there are people who don't have a risk of illicit drug history who have a lot of problems with opioids.

So all of these things increase risk.

Page 161 And they work --1 0. 2 MR. ARBITBLIT: Objection. 3 Q. -- they work together to --I'm sorry, there --4 Α. 5 MR. ARBITBLIT: I need to interject, Counsel. The same principle of duplicative 6 7 questioning applies not only to the articles, but the fact that this witness answered the identical 8 9 line of questioning in the New York deposition at 10 length about risk factors that are part of this 11 multi-factorial analysis several times through your 12 own partner and other counsel. 13 I know -- I don't know whether you're aware of this and asking the questions anyway or 14 whether you're not aware of it. But it's not 15 16 appropriate, and I don't want to have to bother the 17 special master again, but if we keep going through 18 things that have been asked and answered that are not unique to West Virginia - like what are risk 19 20 factors and what's multi-factorial - then we'll 21 call him during the lunch break. 22 Well, you know, I'm -- I MR. HESTER: 23 was -- I was, I think, behaving completely 24 consistently with what the special master

Page 162 contemplated, because I was setting up a general 1 2 point and then I was going to turn to a discussion 3 of West Virginia. MR. ARBITBLIT: Well --4 MR. HESTER: I can't -- it's very hard 5 -- it's very hard to set up the specific questions 6 7 on West Virginia unless I can ask for a baseline understanding and get to a point where the witness 8 9 and I are speaking on the same language about the 10 basic point. That's all I was doing. 11 MR. ARBITBLIT: And you can ask one 12 question, and that is: Are any of the risk factors 13 that you described in your testimony and previous depositions inapplicable to West Virginia, or would 14 15 those same risk factors be applicable? She can answer "yes" or "no", and you 16 17 don't have to repeat at length the same question 18 and answer that extends the deposition. 19 Now you're going to say I'm extending it by arquing. Well, I'm only arquing because 20 21 you're repeating questions that are word for word the same as other depositions of this witness. 22 23 MR. HESTER: Let's just -- let's just 24 keep going. I was -- I was immediately

Page 163 transitioning to West Virginia. 1 2 BY MR. HESTER: 3 Q. So let's -- Doctor Keyes, let's look back at Exhibit 106. And I wanted to point you to page 5 E-52. And I -- it's the middle column on page E-52, really in almost exactly in the middle of the 6 7 page. Sur -- "These surveys also report that factors such as polydrug use and depression are 8 9 associated with nonmedical opioid use in rural 10 areas." 11 Do you see that? 12 Α. In the middle column on -- wait, I'm sorry, 13 page 52. Yeah. E-52, it's the end of the first 14 15 paragraph in the middle column. Oh, I see. "These surveys also report." 16 17 Yes, I see it. 18 And when it refers to poly drug use and depression being associated with nonmedical opioid 19 use in rural areas, is it your understanding that 20 21 there's something particular about rural areas that makes these factors more relevant for nonmedical 22 23 opioid use? 24 Α. Again, this was -- I would consider No.

those risk factors kind of holistically with the rest of the argument of the paper.

- Q. Do you see that poly drug use and depression are two factors that are associated with nonmedical use of prescription opioids in West Virginia?
- A. I don't know -- there may be studies specific to West Virginia that would correlate those exposures.
- Q. Do you have an understanding of that one way or the other?
- A. I believe that the Jennifer -- yeah,
 Reference 20, Jennifer Haven, that might be
 actually Kentucky.

I can't name a study off the top of my head, but I believe that risk factors for prescription opioid use have been studied in West Virginia.

- Q. And do you believe that poly drug use and depression are two of the risk factors for opioid misuse in West Virginia?
 - A. I believe so.
- Q. Do you also -- if you look over at the right-hand column where it refers to "stressors at

Page 165 a macro level such as economic deprivation, 1 2 inequality, structural determination and other 3 pervasive stressors in the environment" --Α. It's discrimination, just so --4 5 Ο. Oh, sorry. Structural discrimination. Is that -- is that observation -- are 6 7 those stressors at a macro level factors that apply in West Virginia: 8 9 Α. Yes. And then the reference in the next 10 Ο. paragraph to family dynamics, the local context, 11 12 which includes "family dynamics," "family 13 composition" "and family stress," are those factors that apply to opioid misuse in West Virginia? 14 15 I would assume that they do. And then there's a reference to a micro 16 Ο. 17 There's reference to "genetic level. 18 vulnerability, neurobiological factors, pharmacological reactivity, personality traits such 19 as sensation-seeking," "psychiatric morbidity." 20 21 Are those factors that would apply to opioid misuse in West Virginia? 22 2.3 Α. Yes. 24 Q. Do you know --

- A. There's also the pharmacological property of the drug to make sure that we're inclusive.
- Q. So those factors in West Virginia would interrelate with the supply to produce a level of OUD incidence?
- A. Right. The supply of opioids, and then the supply causes harm, and that harm might be potentiated based on individual community and macro risk factors.
- Q. Okay. We're just about at 12:45. So why don't we -- why don't we go off the record.

12 VIDEO OPERATOR: Going off the record.

13 The time is 12:42 p.m.

(A recess was taken for lunch after which the proceedings continued as follows:)

VIDEO OPERATOR: Now begins Media Unit 5 in the deposition of Katherine Keyes. We're back on the record. The time is 1:22 p.m.

BY MR. HESTER:

Q. Doctor Keyes, are you aware that a significant volume of prescription opioids comes into Cabell/Huntington illegally via drug trafficking?

MR. ARBITBLIT: Objection.

- A. By "drug trafficking," just so we're using the term terminology, can you just describe what you mean by that?
- Q. Sure. What I mean is people who are bringing prescription opioids into the Cabell/Huntington area who do not have authority to distribute prescription opioids.
- A. I'm aware that there is -- that there is drug trafficking. And I think -- I guess my next question would be, what do you mean by "significant?"
- Q. Well, it's a fair question, and I was going to ask you. Do you have any understanding as to the share of prescription opioids that come into the Cabell/Huntington community through drug trafficking as contrasted with lawful distribution?
- A. The data that I have that would speak to that issue that is cited in the report come from national studies on where people obtain opioids who use them, for example, nonmedically.

And so I would look to those sources to see, for example, who -- what proportion of people obtain nonmedical prescription opioids from a drug

Page 168 dealer, and I believe that it is between 10 and 20 1 2 percent, I would say. 3 That would be my estimate. And that's based on the published 4 Ο. literature? 5 Α. Yes. 6 And do you have an understanding as to who is engaged in this illegal distribution of 8 9 prescription opioids in Huntington/Cabell? I don't know specific individuals. 10 11 Do you have an understanding that there are Ο. 12 drug trafficking organizations that are engaged in 13 the distribution of prescription opioids in Huntington/Cabell? 14 15 That drug trafficking organizations exist? I would say I'm not -- I don't have expertise in 16 17 the local drug markets of the Huntington/Cabell 18 community specifically, but I would not dispute the 19 likely scenario that such organizations either, you 20 know, informally or more complex organizations --21 that they do exist in the Cabell/Huntington 22 community. 2.3 You gave the reference before to an 2.4 estimate of between 10 and 20 percent of the

- prescription opioids in the community you thought would be sourced from illegal drug trafficking.
- A. No, I'm sorry, that's -- just if I could correct you, that's not what -- that's not what the 10 to 20 percent was.
 - Q. What's the 10 to 20 percent?
- A. That's the proportion of people in -- in these other studies who report that they receive prescription opioids from a drug dealer.
 - O. I see.

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- A. That's not the total share of prescription opioids that are obtained in that way. I just want to make sure I clarify that point.
- Q. Could you explain what you mean then? If they're not obtained from a drug dealer, they might be obtained indirectly from somebody else who obtained them from a drug dealer? Is that what you mean?

MR. ARBITBLIT: Objection.

A. The 10 to 20 percent figure that I cited is what my memory is of the literature on where people who use nonmedically -- use prescription opioids nonmedically obtain their opioids. And so people who don't obtain their opioids from a drug dealer

might obtain from family or friends or a physician, etc.

- Q. And so getting to this question of what percentage of prescription opioids available in the community of Huntington/Cabell are sourced from illegal drug trafficking, do you have an estimate of what percentage that is?
 - A. I have not seen a study on that topic.
- Q. But you do have an understanding that not all of the prescription opioids that are available in the community were lawfully distributed there?
 - A. I would accept that.

- Q. And do you know the percentage of lawfully distributed versus unlawfully distributed prescription opioids in West Virginia?
- A. "Distributed" meaning how many are available -- I guess my question is: When you say "distributed," how would one obtain those kind data?
- Q. Yeah, maybe that's what I'm trying to ask you. But, well, maybe we can back up.

You have talked about a total supply that, in your opinion, is excessive in the Cabell/Huntington community. Correct?

A. Correct.

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- Q. And that total supply consists of prescription opioids that were distributed from pharmacies to the -- out into the community plus drugs that were illegally distributed into the community? Are those the two sources of the supply?
 - A. I think those are two sources of supply.
 - Q. Are there any others?
- A. I would say -- I mean, if you're saying kind of pharmacy distribution versus all other, you know, there are prescriptions, for example, that are -- that are lawfully obtained that are not through a pharmacy that they might be, you know, obtained from a doctor in another way, for example.

You know, so I just don't want to be --

- Q. So --
- 18 A. -- too --
 - Q. Fair enough. So there would be some --
 - A. There are legal and illegal. I would say those are two.
 - Q. Some portion of the -- some portion of the supply of prescription opioids in Cabell/Huntington

Page 172 comes from medical sources, whether from pharmacies 1 2 -- a person went through a prescription or 3 otherwise coming from medical providers. Correct? Α. 4 Yes. And then another portion of the supply 5 comes from illegal distribution into the community. 6 7 Correct? Α. Correct. 8 9 Q. Is there any other supply that gives rise to the harms you are describing? 10 No. I mean, I think what you're saying is 11 there are legal and illegal sources of prescription 12 opioids, and I would agree with that. 13 And those two together create the total 14 15 supply that gives rise to the harms that you've identified? 16 17 Α. Yes. 18 And -- but you don't know the percentage of illegally distributed versus legally distributed in 19 20 Cabell? 21 My opinion would be that the illegally distributed sources represent a minority of the 22

Q. And what -- what's your -- when you say

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total drug supply.

Page 173 "minority," do you have a number in mind? Are you 1 2 thinking one third, one quarter, one half? I don't 3 know what you're thinking. Sure. Again, I'm drawing on studies that 4 5 -- that -- where people report how often, for example, they receive medication from a drug 6 7 dealer, which is 10 to 20 percent. So I would say that the ballpark for 8 9 the illegal versus legal supply is somewhere in the 10 same range. 11 And so the illegal -- the illegal Ο. 12 distribution expands the total supply of prescription opioids in Cabell/Huntington, right? 1.3 Α. Yes. 14 15 And it expands then the availability of 16 prescription opioids to people in the community, 17 right? 18 Anything that increases the supply increases the availability. 19 20 And that availability is what leads to Ο. 21 misuse and some percentage of harm among misusers, 22 correct? 23 MR. ARBITBLIT: Objection. 24 All -- I would say all availability leads Α.

Page 174 to harm. 1 2 Ο. And in your report at page 48, you refer to 3 counterfeit prescription opioids. I can point you to it. But I just wanted to ask you about that point that you make. 5 6 You recall that you refer at page 48 to 7 illicitly-manufactured prescription opioids? I just want to find the section of the 8 Α. 9 report. Yeah, sorry, I should have pointed you 10 Ο. 11 It's the next to the last paragraph on page 12 48. It's the fourth line down in the paragraph 13 that begins "Finally." Sure. "...fentanyl and other high-potency 14 15 opioids have been adulterating the supply of both heroin and illicitly manufactured opioids." 16 17 Ο. Right. 18 Α. Yes. So I wanted to ask you about this reference 19 to illicitly manufactured prescription opioids. 20 21 What engages in that illicit manufacturing of prescription opioids? 22 23 Who does the manufacturing? Α. 24 Q. Is that illegal drug traffickers?

- A. I would imagine. I don't know the sources of illicitly manufactured opioids.
- Q. And what's the basis for your knowledge about these illicitly manufactured prescription opioids?
- A. There have been reports in the literature of opioids that are not -- are manufactured not from the -- the drug company that makes them.
- Q. So what -- when they're illicitly manufactured, it means that they're being made by a drug dealer or somebody else who does not have the authority to manufacture them?
 - A. That would be my -- yes.
- Q. And what substances are included in these illicitly manufactured prescription opioids?
- A. Can you describe what you mean by "substances?"
- Q. Well, yes, I mean, so prescription opioids have certain chemicals in them. Are these illicitly manufactured opioids different from or the same as the lawfully manufactured prescription opioids?
 - A. I don't know the specifics of that.
 - Q. You are aware that they're at least on

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Page 176 some occasions - are being adulterated with 1 2 fentanyl? 3 Α. Yes. And you understand that if a prescription 4 5 opioid is illicitly manufactured and is adulterated with fentanyl, it would be more deadly than taking 6 7 a prescription opioid that's not adulterated? It would depend on the dose and duration of Α. 8 9 use of the opioid. Well, all things the same, would --10 Q. 11 Α. Sure. 12 Ο. -- would --13 Right. Two pills that are exactly the Α. same, one has fentanyl and one has not, the one 14 15 with fentanyl will be associated with increased 16 harm. 17 And how long has this activity of illicitly Ο. 18 manufactured prescription opioids been going on? 19 I'm not aware. 20 Are these distributed by drug traffickers, 21 I assume? Among other distributors. 22 Α. 23 Ο. Who else aside from drug traffickers 24 distributes illicitly manufactured prescription

opioids to your knowledge?

- A. I mean, I would imagine that they're used in the same informal networks that licitly manufactured prescription opioids would be distributed.
- Q. In other words, once -- when you say "licitly manufactured prescription opioids," you mean once those licitly manufactured prescription opioids leave the pharmacies and go out into the community, they may fall into the network of people who are distributing those illicit -- those lawful prescription opioids?

Is that what you mean?

- A. I mean that once the -- once the prescription opioid has been created, one way that it gets out into the community is it gets released from a pharmacy. But any way that the licitly manufactured opioid gets into the community, it may be distributed in the same types of networks for which illicitly manufactured opioids are distributed.
- Q. I was just trying to make sure we were talking about the same word when we used "distributed" there. You're talking about

- distributed after the lawful pills have left the pharmacy when you're --
- A. That's one way in which pills are distributed. I'm just saying that however the pills get into the community.
- Q. And so are you aware of any particular marketplace in Cabell/Huntington for illicitly manufactured prescription opioids?
 - A. No.

- Q. Do you know how long this practice of illicitly manufactured prescription opioids has been going on?
 - A. No.
- Q. Do you know whether it's increased in recent years, the phenomenon of illicitly manufactured prescription opioids?
 - A. There may be literature on that topic.

MR. ARBITBLIT: I'll just interpose an objection. That's an identical question to the New York deposition. You're doing -- I'm not objecting to the general area. The questions are sufficiently different.

But if the questions are absolutely identical, I have to object.

- Q. What percentage of illicitly -- I'm sorry, let me back up. In the Cabell/Huntington community, am I right that these illicitly manufactured prescription opioids would add to the total supply?
 - A. Yes.

- Q. And do you know what percentage of prescription opioids in Cabell/Huntington are illicitly manufactured?
- A. Again, just based on inference, general inference from existing studies, I would -- my opinion would be that it's a -- it's a small minority.
 - Q. Have you seen any studies on that?
- A. Well, to the extent that, you know, the vast majority of people who receive prescription opioids are doing -- are doing so not from drug dealers or other drug trafficking networks, I would infer that the majority of the prescription opioids that are being supplied are being supplied through one of these other distribution sources.
- Q. And your point is that the vast majority of people who have access to prescription opioids in Cabell/Huntington have gotten them via a

Page 180 prescription from a doctor or other medical 1 2 provider? 3 MR. ARBITBLIT: Objection. Α. What I meant was that the vast 4 5 minority of the prescription opioids that are consumed are illicitly manufactured prescription 6 7 opioids. It would be a different question what 8 9 the rest of the sources are. 10 But you reason into that by -- by reasoning that the vast majority of prescription opioids in 11 12 Cabell/Huntington are in that community because 13 there was a prescription for them? 14 MR. ARBITBLIT: Objection. 15 I reason into it based on the existing data of where people who used nonmedically received 16 17 their prescription opioids. 18 Do you agree that this -- these illicitly manufactured prescription opioids are another 19 source of potential harm in Cabell/Huntington? 20 21 Α. Yes. And do you know what percentage of opioid 22 use disorder from prescription opioids in 23 24 Cabell/Huntington is attributable to counterfeit

pills?

- A. Again, I would -- my opinion would be that it's a small percentage and that most people who use counterfeit pills are probably using noncounterfeit pills as well.
 - Q. But you don't have --
- A. My knowledge of opiate use disorder, it would be difficult to maintain an addiction solely on illicitly manufactured opioids. I would imag -- there -- people are using both licitly manufactured and illicitly manufactured who have an opioid use disorder on prescription opioids.
- Q. Would you agree that if somebody took a illicitly manufactured prescription opioid that was laced with fentanyl, it would increase the risk of death?
- A. Compared to an ill -- compared to a prescription of --
- Q. All other -- all other things equal, somebody takes a prescription opioid or a number of prescription opioids and in one scenario, they take them without them being lawfully manufactured. In the other scenario, they're illicitly manufactured and laced with fentanyl, that in the second case,

Page 182 there's a higher risk of death? 1 2 Right. Well, what I would say is that if 3 you had two identical pills that were identical in all other ways except the one had fentanyl in it, 5 the one that had fentanyl in it would be more likely to result in harm. 6 Let me ask you to switch subjects a little bit with me. I wanted to ask about your estimates 8 9 of opioid deaths in Cabell and in West Virginia. First of all, let's just set the table. You're not 10 11 a medical examiner, right? I am not a medical examiner. 12 Α. 13 And you don't have any expertise yourself Q. in determining causes of death? 14 15 Α. I would say that --16 MR. ARBITBLIT: Objection. 17 -- I do have. That's what epidemiologists Α. 18 do. 19 Okay. So you -- you determine causes of 20 death by looking at aggregate populations, but you 21 don't have expertise in determining the cause of death of an individual? 22 2.3 MR. ARBITBLIT: Objection. 24 I would say that that's part of my Α.

Page 183 expertise, is evaluating the reliability and 1 2 validity of those types of assessments. 3 Q. Let me ask you to look at page 50 of the And this is where you develop an estimate 4 5 of overdoses directly and indirectly attributable to prescription opioids in West Virginia and Cabell 6 7 County, right? Α. Yes. However, just as a point of 8 9 clarification, this report does not have the 10 updated numbers in it. 11 0. Right. So I was going to ask you about that. 12 13 Α. Okay. So that's -- your corrected --14 Ο. 15 Α. Yeah. 16 Q. -- your corrected tables, which is that 17 Exhibit 104, you have that there? Α. 18 Yes. 19 So that's what I thought we should work off 20 of when I ask some of these questions. 21 Α. Fair. So -- but I wanted to ask you first about 22 23 the methodology. So there's two types of death

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that you attribute to prescription opioids. One is

Page 184 deaths that you directly attribute to prescription 1 2 opioids, and the other is those you indirectly 3 attribute. Is that right? Α. 4 That's right. And you -- you do this based on a review of 5 death certificates? Is that right? 6 7 In part. That's one of the methodologies Α. used. 8 9 Q. What else did you look at aside from death certificates? 10 11 We also looked at the proportion of people who don't have a prescription op -- well, we look 12 13 -- among those who don't have a prescription opioid listed on their death certificate, we used the 14 15 literature to estimate the portion that are indirectly attributable based on inference from the 16 17 literature. 18 Where did you get the base data for the 19 information listed on the death certificates? 20 Α. The CDC. The National Vital Statistics 21 system. And the death certificates list all of the 22 Ο. 23 substances found in the body at the time of death.

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Is that right?

- A. They list the substances contributing to the death, I believe.
- Q. Is it substances contributing to the death or substances found in the body?
- A. Based on the T codes that I used, I believe that they are contributing to the death.
 - Q. And that judgment is made by whom?
 - A. Usually a medical examiner.
- Q. And so there can be circumstances where somebody at the time of death has multiple drugs in their body and -- first of all, let me ask you that. I take it that's true, right? At the time of death, you could have people with multiple drugs in their body?
 - A. That's right.

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- Q. And there are occasions where the medical examiner lists the factors that contribute to death as more than one drug?
 - A. That's right.
- Q. And your judgment and your methodology was that if -- if prescription opioids were listed as one of the contributing factors, you directly attributed the death to prescription opioids even if there were other drugs also identified as

Page 186 contributing causes? 1 Α. That's right. 3 Q. And so you could have somebody who had a mix of substances that was 99 percent fentanyl and 5 1 percent prescription opioid at the time of death. Right? 6 7 MR. ARBITBLIT: Objection. . I'm saying 99 and 1 percent as a fraction Ο. 8 9 of the drugs in their body. MR. ARBITBLIT: Objection. 10 11 That's a hypothetical. I haven't seen data 12 from the Hunt -- Cabell/Huntington community that 13 would list the percentages of each drug that were 14 15 I'll agree. Maybe I'll ask it a different 16 way that may be better. 17 So you could have a circumstance where 18 the medical examiner identifies fentanyl and 19 prescription opioid as contributing causes of 20 death, right? 21 That's correct. And the medical examiner doesn't list which 22 23 one is primary or which one is secondary, right? 2.4 MR. ARBITBLIT: Objection.

- A. Yeah, in that example, it -- if the fentanyl was in a prescription pill, then both were necessary for the death.
- Q. Well, I was just asking about fentanyl -- let's talk about illicit fentanyl, illegal fentanyl. And --

MR. ARBITBLIT: Sorry.

- Q. -- after 2015 or so, you're aware that there has been a significant spike in illegal fentanyl use in Cabell/Huntington?
 - A. Yes.

Q. And so let's -- I just wanted -- it is hypothetical, but to help illustrate what we're talking about, you could have a death certificate that lists fentanyl and heroin as causes of death in the -- without the medical examiner deciding which was primary and which was secondary.

Correct?

MR. ARBITBLIT: Objection.

- A. Based on the T codes, you know, I think the T codes are all just listed as contributing causes. The idea is that they interact with each other, so that each one was necessary for the death to occur.
 - Q. And --

- A. So if opioids and fentanyl were listed, then both were necessary for the death to occur.
- Q. Well, if they're both contributing causes, one could -- one could be sufficient for the death to occur even if -- even if they're both listed as contributing causes, right?

MR. ARBITBLIT: Objection.

A. I don't think that would be an accurate representation of what occurs at an opioid overdose death, given that -- unless the individual was taking fentanyl alone, they're taking fentanyl that's been mixed with heroin, and so both were used at the same time, you know.

An individual's not using fentanyl alone -- do you know -- if that makes sense.

- Q. So -- so you're saying that the medical examiner identifies, let's say, the scenario of heroin and fentanyl together, the medical examiner would identify them both as contributing causes and so you would see both as causes that were required for the death?
 - A. Yes.

Q. And the same for prescription opioids? If the medical examiner lists a prescription opioid as

a contributing cause along with fentanyl, you would see the prescription opioid as a cause of the death?

- A. Yes.
- Q. Even though it's not the only cause, right?
- A. Right.

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- Q. And so you could have a death that is due to multiple causes beyond prescription opioids?
- A. The question is whether the death would have occurred without the prescription opioid. So if someone is using prescription opioids and benzodiazepines, for example, which is a common combination, it's unlikely that if the person took benzodiazepines alone, they would have died. But the opioid and the benzodiazepine together interacted to cause the death.
- Q. But you could have a circumstance where somebody could take a prescription opioid and fentanyl together and the fentanyl might be a sufficient cause of death, but heroin was also identified as a -- I'm sorry, prescription opioids is also identified as a cause of death. Right?

 MR. ARBITBLIT: Objection.
 - A. Usually that would happen because they were

taken together. So again, I would say that the person would not have taken fentanyl had the prescription opioid not been there.

Do you know what I'm saying? So I would say when the prescription opioid is listed as a cause of death, it's a reliable methodology to consider it a cause of death.

- Q. Well, when you -- when you talk about "cause" in this -- in this circumstance, you're not talking about sole cause or the only cause. You're talking about one among potentially a number of causes. Correct?
 - MR. ARBITBLIT: Objection.
- A. The definition of "cause" is a factor without which the outcome would not have occurred.
 - Q. So --

- A. So there could be multiple causes.
- Q. There could be multiple causes for a certain event, correct?
 - A. There can be multiple causes, but it's not a cause unless the outcome would not have occurred without it.
 - Q. But the medical examiner doesn't decide whether an outcome would have occurred without the

Page 191 individual cause, right? 1 2 MR. ARBITBLIT: Objection. 3 Α. I think that's probably what the medical examiner is doing with the contributing causes 4 list. 5 And what's the basis for your knowledge of 6 7 that? My experience working with death 8 9 certificates. So if you have a death certificate that 10 11 lists prescription opioids and fentanyl as contributing causes, you attribute that death 12 13 directly to prescription opioids, right? 14 Α. Yes. 15 Do you also attribute that death directly to fentanyl? 16 17 If I were to do a different analysis than Α. 18 the one that I did, sure. Because -- because you would also see the 19 Ο. 20 fentanyl as a cause of the death? 21 Α. Both substances caused the death. Now, let's talk about indirect attribution. 22 23 So where you have a death where the sole cause is 24 listed as fentanyl, you indirectly attribute a

percentage of those deaths to prescription opioids?

A. Yes.

- Q. And what's the methodology by which you do that?
- A. I tried to be conservative in my estimate and used the NSDUH data, the National Household Survey on Drug Use and Health, and estimated the portion of nonprescription opioid users who used a prescription opioid prior to the nonprescription opioid as an estimate of the transition from prescription opioid to nonprescription opioid.
- Q. So your assumption in your methodology is that somebody would not have transitioned to fentanyl without a prescription opioid as a prior sequence?

MR. ARBITBLIT: Objection.

- A. I don't think I have to make that assumption for the -- in the methodology. It's an estimate of indirect -- indirect proportion, a conservative estimate of the indirect proportion that would be attributable based on that association.
- Q. Is there -- is there any study in the published literature that has done this, that has

- engaged in that indirect attribution of fentanyl test for prescription opioids?
- A. Certainly. If you look at the opioid simulation literature, these kinds of estimates are used routinely and reliably.
- Q. So when we talk about causes for a death from fentanyl, I take it you would agree that prescription opioids are not the only cause of a death from fentanyl. Right?
- A. Prescription opioids were necessary for the death to occur, and it interacted with other drugs.
- Q. Prescription opioids -- I'm sorry, go ahead.
- A. So that is how I would frame the causation piece of that.
- Q. I'm talking about indirect, though, where the --
- 18 A. Oh.

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- Q. -- where the only cause of death is listed as fentanyl.
- A. Okay. I'm -- I apologize. Cause of death from fentanyl -- right. I would say --
- Q. So there's other -- there's other causes of the death from fentanyl aside from prescription

Page 194 opioids, right? 1 2 Α. In terms of indirect attri -- the deaths 3 that are indirectly attributed? Ο. 4 Yes. Those would be the multi-factorial deaths, 5 Α. 6 yes. So the multi-factorial deaths of somebody from fentanyl would include the social factors and 8 9 individual factors and environmental factors we discussed before? 10 11 Yeah, depending on the -- on the person, 12 there are -- there's only one necessary cause of 13 death, and that's opioid exposure. 14 And whatever factors also potentiated 15 the risk after the exposure to opioids, there are a number, including fentanyl exposure. 16 17 But you're assuming then that the opioid 0. exposure is the necessary cause that leads somebody 18 19 to fentanyl? 20 Opioid exposure is a necessary cause of Α. 21 opioid overdose death. 22 But opioid exposure is not a necessary 23 cause of fentanyl, is it? 2.4 MR. ARBITBLIT: Objection.

- A. Fentanyl is an opioid.
- Q. Okay. So I -- maybe back up. Prescription opioid exposure is not a necessary cause of fentanyl -- of deaths from fentanyl, right?
 - A. That's correct.

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Q. And there are other factors that contribute to a death from fentanyl, including individual factors and social factors and economic factors, right?

MR. ARBITBLIT: Objection.

- 11 A. There certainly could be other factors
 12 involved.
 - Q. And also you have a drug dealer that's lacing heroin with fentanyl, that's part of the causation chain, too, right?
 - A. It would depend on the death.
 - Q. Do you know how fentanyl typically gets into the supply chain? Is it typically by adulteration of heroin?
 - A. Yes.
 - Q. Typically users are not seeking out fentanyl by -- on its own, correct?
 - A. Typically.
 - Q. So that in a typical case where a drug

dealer laces heroin with fentanyl, the user isn't even aware of that, correct?

- A. I don't think I would make that blanket statement just based on what we know about drug use. Sometimes users are unaware.
 - O. But users don't --

- A. Sometimes users are aware, and they seek it out.
- Q. But is it your understanding that the general case is that users don't seek out fentanyl?
- A. I don't think that's my understanding. I think it depends on -- on the individual and the drug market. I mean, there's certainly a lot of literature about heroin users who prefer stronger heroin.
- Q. So these other causes that we've been discussing, your methodology isn't undertaking to control for the other causes that might also contribute to fentanyl deaths, right?

MR. ARBITBLIT: Objection.

A. The methodology in assigning attributable and -- directly attributable and indirectly attributable, these factors would not be confounders. There would not be a statistical

control for them. That would not be appropriate based on my methodology.

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Q. But you're not -- you're not trying to measure or figure out the other factors that might also be attributable to the death.

MR. ARBITBLIT: Objection.

- A. My methodology was to assign direct and indirect attribution, and so these other factors would not be relevant to that particular analysis.
- Q. But you would agree these other factors that we've been discussing are other factors that would be contributory causes to fentanyl deaths.

MR. ARBITBLIT: Objection.

- A. Again, the only necessary factor is the exposure to the opioid, and that's what I was focused on.
- Q. Well, when you say "exposure to the opioid," because fentanyl is an opioid?
- A. My analysis was to assign direct and indirect attribution to prescription opioid.
- Q. But the prescription opioid is not -- is not necessary or sufficient for a fentanyl overdose, is it?
 - A. Not for a fentanyl overdose, no.

- Q. Because -- because somebody might be taking -- might be overdosing on fentanyl without ever having taken a prescription opioid, correct?
- A. That's -- that's generally consistent with a risk factor. They -- in general, there can be -- you know, the same as smoking and lung cancer. There are lots of people who get lung cancer and never smoked. And there's lots of people who die of fentanyl and other opioid overdose who don't use prescription opioids, and that doesn't make prescription opioids less of a cause.
 - Q. But they're -- they're not the only cause?
- A. Prescription opioids are not the only cause of opioid overdose.
- Q. And they're not the only cause of heroin overdoses?
 - A. That's correct.
- Q. Let me ask you to look at your report, page 49, please. At the very bottom of the page, you refer to a "prevalence estimate that ranged from 45.5 in 2006 to 62.8 in 2014." Do you see that?
 - A. I do.

- Q. What's a prevalence estimate?
- A. So that is the -- that's the proportion of

people in that subgroup who experienced the outcome of interest.

- Q. Okay. So to tie that to these specific circumstances, are -- is that stating that in 2006, for instance, 45.5 percent of those who ended up with a fentanyl overdose began their opioid use with prescription opioids?
- A. That estimate refers to the proportion of heroin users in the NSDUH data in 2006 who began with nonmedical prescription opioid use.
- Q. Okay. So that it's NSDUH data focusing on heroin users; is that right?
 - A. Yes.

- Q. And so it's NSDUH data that reflects that heroin users were -- sorry. It's NSDUH data that reflects that 45.5 percent of heroin users in 2006 initiated their opioid exposure with prescription opioids?
 - A. Yes.
- Q. And the -- for the 2014 number, same question. Does that reflect that 62.8 percent of the heroin users initiated their use of opioids with prescription opioids?
 - A. Yes.

- Q. And it's measuring prevalence, not instant
 -- incident. So it's measuring the community of
 people in a given point in time who gave that
 answer, correct?
- A. Well, in this circumstance, it's measuring incidence and prevalence, because we're looking at lifetime heroin use and lifetime initiation of nonmedical prescription opioid use.

So it's an incidence measure --

Q. So --

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- A. -- versus a prevalence measure.
- Q. In your report at 48, page 48, you say toward the bottom of the page "that approximately
 70" to "80% of individuals who use heroin began
 their opioid-using trajectories with prescription
 opioids." Do you see that?
- A. Yes.
- Q. And so these numbers are lower than that 70 to 80 percent figure, correct?
 - A. That's correct.
- Q. And these -- these numbers are the ones you applied in estimating the indirect attribution of fentanyl deaths?
 - MR. ARBITBLIT: Objection.

Page 201

A. Yes. I wanted to apply the most reliable methodology based on my field of expertise in opioid simulation, and we often try to apply conservative estimates in these circumstances.

And given that I know that the NSDUH data underestimates heroin use and would thus provide me with the most conservative estimate of this -- this parameter that I was looking to essentially simulate, I relied on -- on a conservative approach, as I outlined in the report.

Q. So looking back at Exhibit 104, which is your corrections, and looking at the table here, you ended up -- and maybe -- I'm looking at the first page of Exhibit 104.

You ended up with an estimate for -well, I'm sorry. This is -- this table is dealing
with opioid use disorder; it's not dealing with
death estimates. Right?

- A. Figure 13 is opioid use disorder.
- Q. Okay, sorry, we'll go back to that.
- A. Figure 16 is the deaths.
- Q. Right, okay, sorry. All right. I'm with you.
 - So you're not able to tell, looking at

Figure 16, what percentage of those deaths involved illegally-trafficked prescription opioids, right?

A. No.

- Q. And you don't know the percentage -- so you don't know the percentage of the deaths that are attributable to illegally-trafficked prescription opioids?
- A. Again, as I testified, I think it would be small. But the WONDER data does not distinguish illegal from legal. But based on other data, I think we can infer that it's a minority.
- Q. But putting it another way, the death certificates that are the basis for this analysis that you've done, they don't distinguish between somebody who has, at the time of death, an illegally-distributed prescription opioid in them as compared to a legally-distributed?
 - A. No.
- Q. And is it your understanding that the vast majority of these deaths of -- that you attribute to prescription opioids arise out of misuse?

 MR. ARBITBLIT: Objection.
- A. There's such overlap between medical and nonmedical prescription opioid use that I think

that it would be inappropriate to characterize the vast majority as misuse.

Q. Do you know what percentage of these deaths that you attribute to prescription opioids are due to misuse as contrasted with the percentage due to use under legitimate doctor prescriptions?

MR. ARBITBLIT: Objection.

- A. Given the overlap of medical and nonmedical use, I would say that very few would be attributable only to misuse.
- Q. Now, but my question is a little different.

 Do you know the percentage of deaths in this chart that are attributable to people who took prescription opioids solely as prescribed?
 - A. No.

- Q. Do you know how many of the deaths that you show here on Figure 16 involved counterfeit prescription opioids?
- A. Again, I would estimate that do be a small number. But it -- but the death certificate does not provide that information.
- Q. So putting it another way, the death certificate doesn't reflect whether the prescription opioid that's listed as a cause of

death was a counterfeit or illegally-manufactured prescription opioid?

A. To be honest, I don't know a single case of someone with an opioid use disorder who solely used counterfeit prescription opioids. I mean, as far as I know, the -- everyone who uses counterfeit prescription opioids has also used noncounterfeit prescription opioids, so I don't think there would be --

I think it would be highly unlikely that there would be any case of someone for whom a prescription opioid overdose death was not attributable to prescription opioids, whether counterfeit or not.

I don't think that distinction would be highly relevant, from me forming my opinions.

- Q. Now, I wasn't asking whether it would be relevant. I was just asking whether you knew. And I take it you don't know whether the deaths attributed here to prescription opioids, you don't know what percentage of those involved counterfeits.
 - A. No.

Q. Doctor Keyes, let me ask you about your

opinion on the transition from prescription opioids to heroin and it's -- I think it probably starts around page 46-47. And I guess maybe I'll point you to page 47, at the bottom of that page.

And there's a paragraph with a second sentence that says, "A small but significant proportion of individuals who use prescription opioids progress to heroin use." And then over on the next page, 48, you say at the end of that first carryover paragraph, you say, "it is reasonable to conclude that there is a causal relationship between prescription opioid use and heroin use." .

Do you see that?

A. I do.

- Q. And are these opinions you also stated in the New York litigation and in the Ohio litigation?
 - A. Yes.
- Q. Are there any different opinions that you're stating here than those you've stated in those other litigations?
 - A. No.
- Q. Are there any answers that you gave to any questions in the New York litigation or in the Ohio litigation that would differ from the questions I

could ask you here that would be on the same points?

A. Nothing comes to mind.

- Q. Let me ask you -- well, let me ask you first: Have you done any specific study related to West Virginia of the transition from prescription opioid use to heroin use?
- A. I've reviewed studies that are specific to West Virginia. But I have not myself collected data in West Virginia.
- Q. Which ones do you have in mind that are specific to West Virginia?
- A. I believe the Allen study is specific to West Virginia. And I may cite others in here as well.
- Q. Well, let me be a little more concrete on this just to make sure we're on the same page.

At page 46, you refer to -- it's the second paragraph under Sub I, and you refer to "Cross-sectional studies of samples recruited based on nonmedical prescription opioid use" "consistently find strong signals of a relationship." Do you see that?

A. I do.

- Q. And you're referring there to 16 studies that you looked at on this question of the transition from prescription opioids to heroin?
- A. Not exactly. I reviewed 16 studies. Not all of those were cross-sectional studies.
 - Q. Okay.

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- A. So there were longitudinal, cross-sectional, ethnographic, kind of mixed in those 16.
- Q. But those 16 studies are the basis for your opinion on this transition from prescription opioids to heroin?
 - A. Yes.
- Q. And did any of those 16 studies specifically address West Virginia?
 - A. I don't believe so.
- 16 O. And --
 - A. Well, I'm sorry. I guess I would qualify that by saying that some of the studies included West Virginia data. A fair number of the studies included West Virginia data. But --
 - Q. Fair enough.
- 22 A. But not exclusively.
- Q. But none of them looked specifically at the West Virginia population specifically on this

Page 208 question of transition from prescription opioid to 1 2 heroin? 3 Α. No. And I take it none of them look at the 4 5 transitions from prescription opioid use to heroin in Cabell/Huntington? 6 That's correct. Although the Allen study, Α. I think, is specific to Cabell. 8 9 Q. Let's see. The Allen study that you refer 10 to, I didn't have that in my list of 16. 11 It's not in the 16. Α. 12 Q. Okay. 13 It's some data that helped me form my opinions. That study --14 15 What is -- what is the Allen study? Do you 16 know? Do you have that cite handy? 17 It -- I can find it in my -- in the list. Α. 18 Maybe you can just point me to that so I O. have it. 19 20 I'm looking at the reference list to find Α. 21 it. I'd have to go over it in more detail, 22 but I'm sure I could send it to you. It's on my 23 24 Materials Considered list.

- Q. I'm sorry, Doctor, could you -- my computer froze for a minute. Could you say that again?
- A. I'm not seeing it in the reference list, but I don't have time to carefully go through it.

 It's on my Materials Considered list. I'm sure we can send it to you. It's a paper on injection drug use in Cabell.
- Q. Okay. And just to be clear, it's not one of the 16 that you cite at page 46.
 - A. That's right.

Q. Okay. Let me ask you to look, please, at Exhibit 37.

KEYES DEPOSITION EXHIBIT NO. 37

("Psychoactive substance use prior to the development of iatrogenic opioid abuse: A descriptive analysis of treatment-seeking opioid abusers" by Cicero, et al. dated 2017 was marked for identification purposes as Keyes Deposition Exhibit No. 37.)

- Q. And actually, before we get to that one, let's also have you pull out Exhibit 47.
 - A. Okay.
 - Q. Let me ask you about Exhibit -- no, I'm

Page 210 sorry, it's not Exhibit 47 at all. Sorry. 1 2 apologies. Exhibit 34. Could you pull that one 3 out, please? Sorry for the confusion. Α. 4 All right. KEYES DEPOSITION EXHIBIT NO. 34 5 ("Association of Nonmedical Pain 6 7 Reliever Use and Initiation of Heroin Use in the United States" by Muhuri, 8 9 et al. dated August 2013 was marked 10 for identification purposes as Keyes 11 Deposition Exhibit No. 34.) Exhibit 34, just for the record, is a paper 12 Q. 13 by Pradip Muhuri and others entitled "Associations of Nonmedical Pain Reliever Use and Initiation of 14 15 Heroin Use in the United States." 16 Α. Yes. 17 And Doctor Keyes, you're familiar with this 0. 18 study? I am. 19 Α. 20 And to your understanding, did the findings Ο. 21 of this study apply fully to West Virginia? Generally. You know, the specific 22 Α. 23 percentages may vary a bit. 24 Q. But the basic findings are ones that you

Page 211 would agree apply to West Virginia? 1 2 Yeah. I mean, I would say they have --3 they have estimates of heroin initiation here that I think would be higher in West Virginia than what 5 they report here. What's your basis for saying that? 6 Ο. 7 My own estimate of the prevalence of OUD in the Cabell/Huntington community. 8 9 Ο. And is that stated in your report 10 somewhere? 11 Α. Yes. 12 Where is that stated? 13 Page 41, the number of individuals with OUD. I estimated that for each year. 14 15 This is -- let me point you to page 47 of your report. And it's -- it's the conclusion I 16 17 pointed you -- or the sentence I pointed you to 18 before, I think, on page 47 toward the bottom where 19 you say, "A small but significant proportion of 20 individuals who use prescription opioids progress 21 to heroin use." 22 Do you see that? 23 Α. I do. And you cite the Muhuri paper, Exhibit 34, 24 Q.

Page 212 is the basis for that statement? 1 2 Α. Yes. 3 Q. And so does the Muhuri report reflect what you mean when you say "a small but significant 4 5 proportion of individuals progress" -- progress "to heroin use"? 6 Α. Yes. Okay. And so you would see that 8 9 as applicable to West Virginia? I think the sentence, "A small but 10 significant portion of individuals who use 11 12 prescription opioids progress to heroin use" would 13 be applicable to West Virginia. And let me ask you to look at Muhuri, 14 15 please, page 13. 16 Sorry, I noticed when looking at this yesterday, it has no page numbers, of all things. 17 18 At least on my copy. You might be lucky --19 It has page numbers. Α. 20 Oh, you have page numbers? Ο. 21 Α. Uh-huh. Wow. You're living better than I am then. 22 0. 23 So go to page 13. I think it's page 24 13. It's under the heading "Pattern of Heroin

Page 213 Initiation During the 5-year Period after NMPR 1 2 Initiation" --3 Α. That's not my page 13. Is that 12? Ο. Are you referring to the text or table? 5 Α. I'm in the text. 6 Q. 7 Okay. Α. And there's a heading for "Pattern of 8 9 Heroin Initiation During the 5-year Period after NMPR Initiation." It's toward the back of the 10 paper. It's above Table 5. 11 12 Α. I see. I'm here. And you see the section, the small section, 1.3 O. that's headed "Pattern of Heroin Initiation" --14 15 Α. Yes. 16 Ο. And the sentence that I wanted to ask you about is: "Accumulation of these estimates 17 18 indicates that, only 3.6 percent of NMPR initiates" 19 "had initiated heroin in first 5 years following first NMPR use." Do you see that? 20 21 Α. I do. The first question is: To your 22 23 understanding, does that finding apply to West 24 Virginia, the population of West Virginia?

- A. I would imagine it would be slightly higher because the rate of heroin initiation is generally higher.
- Q. And you would say "slightly higher." How much higher?
- A. I mean, hard to know for sure, but I would -- I would guess at least twice as high.
 - Q. Not higher --

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- A. Somewhere between -- somewhere between this estimate and twice as high would be my -- my reasonable estimate.
 - Q. Have you seen any study that reflects that?
- A. The Allen study estimated at least the number of injection drug users, of which 60 percent would be heroin users, and I think had a higher proportion than this. And that's --
- Q. But I'm asking specifically about this question of initiation of heroin following nonmedical prescription drug use. And do you have any studies aside from this one that reflects an initiation rate for heroin use following NMPR initiation?
- A. No. This is -- this is my -- my reasonable estimate based on the data that I've seen. But I

don't have any specific studies of this question. I'm inferring from other literature.

- Ο. And you cite Muhuri in your report for the proportion of individuals who used prescription opioids who progressed to heroin. Right?
 - Α. Yes.

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And when you say "use," in that sentence, you're talking about misuse, right?

MR. ARBITBLIT: Objection.

- There's a -- there is a lot of overlap between medical and nonmedical use, and so I -- I think just general prescription opioid use in terms of heroin use.
- But Muhuri's is focused on progression from nonmedical use --
- A large portion of those users are also medical users, based on the literature.
- But Muhuri is studying the progression of nonmedical use to heroin use, right?

MR. ARBITBLIT: Objection. Counsel, now we're off West Virginia and you're repeating the Muhuri questions that have been asked at two different depositions.

I'd ask that you move on.

Page 216 MR. HESTER: I'm just -- I'm really 1 2 just trying to tie it back to the point the witness 3 made about West Virginia. MR. ARBITBLIT: No. No, you're not. 4 5 If you --6 MR. HESTER: Yes, I am. 7 MR. ARBITBLIT: Well, there was nothing about West Virginia in that guestion, 8 9 Counselor. 10 MR. HESTER: I -- I'm only responding 11 to what she said. I had expected her to agree. 12 mean --13 BY MR. HESTER: Doctor Keyes, maybe just a simple point. 14 15 You're agreeing, I believe, that the statement --16 that the finding in here, in the Muhuri report that 17 we just looked at, you would agree that that's the 18 only study that you've seen that reflects that progression that applies to West Virginia? 19 20 MR. ARBITBLIT: Objection. Asked and 21 answered. Misstates the record. 22 Yeah, I think I -- there are other studies 23 cited in my report about this progression. 24 Q. No, I'm asking you, have you seen -- have

Page 217 you seen any other report that reflects the same 1 2 measurement here that applies to West Virginia? 3 I'm trying to ask specifically about West Virginia. Does the -- does the Muhuri finding 4 here that we've just been looking at, does that 5 apply to West Virginia? 6 7 MR. ARBITBLIT: Asked and answered. Α. I would estimate that the initiation of 8 9 heroin use would be slightly higher. It would be 10 somewhat higher in West Virginia based on 11 well-accepted patterns of use. And your point is, it may be in the range 12 Q. of 5 percent instead of the 3.6 that Muhuri states? 1.3 14 MR. ARBITBLIT: Objection. 15 3.6 times 2 would be higher than 5 percent. Okay. So that would be on the upper bound 16 Ο. 17 of what you think it would be, in the range of 7 18 percent? I would say, yeah, about 7 -- yes. That's 19 my opinion. 20 21 Ο. And let me ask you to look at -- now at Exhibit 27, please. 22 23 I haven't opened that one, right? Α. 24 I think I may have asked you just to open Q.

Page 218 it. It's entitled Increased use of heroin as an 1 2 initiating opioid of use by Cicero. Did I ask you 3 to open that one? That was an exhibit -- there was a Cicero 4 5 article that was Exhibit 37 that was "Psychoactive substance use prior to the development of 6 7 iatrogenic opioid abuse?" Yeah, this is another one then. Ο. 8 9 Α. 27. Okay. KEYES DEPOSITION EXHIBIT NO. 27 10 11 ("Increased use of heroin as an 12 initiating opioid of abuse" by Cicero, 13 et al. dated 2017 was marked for 14 identification purposes as Keyes 15 Deposition Exhibit No. 27.) 16 Ο. So Exhibit 27, just for the record, is a paper by Cicero, Ellis and Casper entitled 17 18 "Increased use of heroin as an initiating opioid of 19 abuse." Doctor Keyes, have you seen this study 20 before? 21 Α. Yes. 22 And do you see -- let me point you to page 23 64, which is the second page of the document. I wanted to point you to the right-hand column, the 24

second sentence. It says, "Only 8.7% of opioid initiates who began regular use in 2005 started with heroin, but its use sharply increased thereafter to the point where in 2015, heroin as an initiating opioid was at its highest point, 33.3%."

Do you see that?

A. I do.

- Q. And do you know, or do you have an understanding that this finding applies to the West Virginia population?
- A. I wouldn't -- I wouldn't disagree that the results would generalize.
- Q. And there's also a further reference just after what I read to you. It says, "with no evidence of stabilization." Do you see that?
 - A. I do.
- Q. Do you have an understanding that the use of heroin as an initiating opioid has increased in West Virginia since 2015?

MR. ARBITBLIT: Objection.

A. My understanding is that, you know, even based on this, it's still 70 percent of people who start with prescription opioids, which is what my report stated. That has increased. I don't know

Page 220 of any particular data in West Virginia, although I 1 2 would imagine that similar trends are emerging in 3 that area. I was asking -- there's a -- your -- I believe you said that you believe -- or you have no 5 reason to disbelieve that these results reported 6 7 here - heroin as an initiating opioid increasing to 33 percent by 2015 - you would expect those results 8 9 would apply to the West Virginia population? 10 Α. That's right. 11 Ο. And my question is: Do you have any 12 information as to whether the percentage of heroin as an initiating opioid has increased since 2015 in 13 the U.S. population? 14 15 Α. I don't. And do you have any knowledge as to whether 16 17 the use of heroin as an initiating opioid has 18 increased in West Virginia? 19 Α. No. 20 MR. ARBITBLIT: We've been going about 21 an hour and 15. You want to take about a five-minute break? 22 2.3 MR. HESTER: Sure. Sure, that's fine. 24 MR. ARBITBLIT: Thank you.

Page 221 VIDEO OPERATOR: Going off the record. 1 2 The time is 2:32 p.m.3 (A recess was taken after which the proceedings continued as follows:) 4 5 VIDEO OPERATOR: Now begins Media Unit 6 in the deposition of Katherine Keyes. We are 6 7 back on the record. The time is 2:46 p.m. BY MR. HESTER: 8 9 Q. Doctor Keyes, let me ask you to look at 10 Exhibit No. 37. This is a paper by Cicero, Ellis and Casper entitled "Psychoactive substance use 11 12 prior to the development of iatrogenic opioid use." 13 Do you have that one there? I do. 14 Α. 15 And let me ask you to look at page 2 --16 well, I should ask you first, have you seen this 17 study before? I have. 18 Α. Let me ask you to look at page 243, which 19 is the second page of the paper. And there's a --20 21 it's under Discussion and Conclusions, and it says, "The results of this study indicate that only 4% of 22 23 those who experience their first opioid via a 24 physician's prescription were truly drug naive.

Page 222 Rather, more than 95% had significant psychoactive 1 2 drug experience prior to being prescribed their 3 first opioid." 4 Do you see that? 5 Α. I do. Do you understand that that finding, as 6 7 stated here, applies to the West Virginia community? 8 9 I would take that -- I would -- I think we 10 can proceed with that assumption. 11 Ο. And at -- later on in the same paragraph, 12 it says, "70% had experience with other types of 13 drugs; and, second, on average, four to five different types of drugs were used prior to initial 14 15 opioid exposure from a prescription." 16 Do you see that? 17 Α. I do. And to your understanding, does that 18 19 finding also apply to the West Virginia population? 20 Α. To my understanding. 21 Q. Let me ask you to look at Exhibit 46, 22 please. 23 Let me see if this is one we've already 24 opened?

- A. I believe it is. I don't have 46.
- Q. Yes, I believe we have looked at 46 before.
- 3 This is -- for you to find this one, it's by
- 4 McCabe, and it's called "A prospective study of
- 5 nonmedical use of prescription opioids during
- 6 adolescence."
- 7 A. I have it. Can you just tell me again what
- 8 | Exhibit No. this is? I'm just going to write it at
- 9 the top.

- 10 Q. Yeah, 46.
- MS. DO AMARAL: And we'll just note
- 12 | for the record that the exhibits, once they come
- out of their pouches, don't have exhibit numbers on
- 14 | them, so we're having some difficulty identifying
- 15 which one we're looking for.
- MR. HESTER: Right.
- Q. So just feel free, Doctor Keyes, to write
- 18 | the numbers on there.
- 19 A. Thank you.
- Q. And I wanted to point you to page 6 of this
- 21 paper. And it's the start of the second paragraph.
- 22 It says, "Among adolescents who engaged in
- 23 | past-year NMUPO, approximately 95% also used other
- 24 | substances and the majority simultaneously

Page 224 co-ingested prescription opioids with other 1 2 substances." 3 Do you see that? T do. Α. 4 5 And to your understanding, does that finding apply to the West Virginia community? 6 7 I would -- I would assume that it generalizes. 8 9 Ο. Let me ask you to look at Exhibit 28, This is, again, another new one, I think. 10 please. 11 This is new. Α. KEYES DEPOSITION EXHIBIT NO. 28 12 13 ("Relationship between Nonmedial 14 Prescription-Opioid Use and Heroin 15 Use" by Compton, et al. dated 1-14-16 was marked for identification purposes 16 17 as Keyes Deposition Exhibit No. 28.) 18 Α. Okay. 19 For the record, Exhibit 28 is by -- a paper 20 by Compton -- Wilson Compton and others entitled 21 "Relationship between Nonmedical Prescription-Opioid Use and Heroin use." Have you seen this 22 paper before? 23 24 Α. Yes.

- Q. And let me ask you to look at page 160 of the document, please. And there's a statement at the -- under Conclusions -- well, maybe before I ask you about the specifics, who is Wilson Compton? Do you know?
- A. He's the deputy director of the National Institute of Drug Abuse.
 - Q. And is he still in that position?
- A. As far as I know. But I could be wrong about that.
- Q. And under Conclusions at the end of the first -- first paragraph, he says, "heroin use among people who use prescription opioids for nonmedical reasons is rare and the transition to heroin use appears to occur at a low rate." Do you see that?
 - A. I do.

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- Q. And to your understanding, does that conclusion apply to West Virginia?
- MR. ARBITBLIT: I'm just going to object to the reading of the partial sentence.
- A. Yes, that's a good point. Could we read the entire sentence?
 - Q. Yeah. Why don't we read the whole thing?

Page 226 "Yet, although the majority of current heroin users 1 2 report having used prescription opioids 3 nonmedically before they initiated heroin use, heroin use among people who use prescription 5 opioids for nonmedical reasons is rare, and the transition to heroin use appears to occur at a low 6 7 rate." Do you see that? 8 9 Α. T do. And does that conclusion stated here apply 10 Ο. to the West Virginia population, to your 11 12 understanding? 13 MR. ARBITBLIT: Objection. Again, as I stated, I think the rate of 14 heroin use is -- is higher in West Virginia than in 15 16 other areas. 17 And so you would say it's somewhat higher Ο. 18 than you would see in the entire U.S.? 19 That's right. Α. 20 What are the reasons that the rate of Ο. 21 heroin use is higher in West Virginia? I mean, in my opinion, it's because the 22 23 supply of prescription opioids in the 1990s set the

stage for a lot of people who had opioid use

Page 227 disorder. 1 2 Ο. There's also -- there's also been an 3 increase in the supply of heroin in West Virginia; is that right? There have been increases in the supply of 5 heroin nationally. I haven't seen data that's 6 7 specific to West Virginia. Have you analyzed that question of how much 8 Ο. 9 the supply of heroin has increased in West Virginia? 10 11 My opinion is that people don't use heroin 12 on a lark. It is due to the supply of prescription opioids that set the stage for a whole population 1.3 of people to be vulnerable to opioid use disorder. 14 15 So once that stage was set, any increase in the supply of heroin had an active 16 17 market to supply to. 18 O. I think I asked you a different question. All right, I apologize. 19 My question was, have you looked -- have 20 Ο. 21 you looked at the question of how much the heroin 22 supply has increased in West Virginia? 2.3 Α. No. 24 Q. And have you looked at the question of how

Page 228 much the price of heroin has dropped in West 1 2 Virginia? 3 Again, I am aware of data on that nationally, but I have not seen West 4 5 Virginia-specific data on price. Let me ask you to look -- so -- so we spoke 6 7 about this one sentence in the -- in the Compton report, and your view is that heroin use is higher 8 9 in West Virginia than in the rest of the country? 10 Α. Yes. 11 And subject to that point, do you agree that this conclusion as stated here applies to West 12 Virginia? 1.3 14 MR. ARBITBLIT: Objection. 15 I think that -- I don't know -- I can't --16 I can't say whether -- that it applies. 17 Do you agree with the statement in this Ο. 18 paper that "heroin use among people who use prescription opioids for nonmedical reasons is 19 20 rare"? 21 Α. Yes, I agree with that. 22 Further down in the third paragraph, 23 there's a first sentence that reads, "In the

majority of studies, the increase in the rates of

Page 229 heroin use preceded changes in prescription-opioid 1 2 policies, and there is no consistent evidence of an 3 association between the implementation of policies related to prescription opioids and increase in the rate of heroin use or deaths, although the data are 5 relatively sparse." 6 7 Do you see that? Α. I do. 8 9 Does that conclusion apply to West 10 Virginia, to your understanding? 11 MR. ARBITBLIT: Objection --No, I think there is sufficient -- I'm 12 Α. 13 sorry, did I miss something? 14 MR. ARBITBLIT: Go ahead. 15 I think that there is sufficient data post-2016 that would -- I think that that 16 17 conclusion -- as noted by Compton, there was 18 insufficient data, but I think now any reasonable 19 epidemiologist would conclude that there is more 20 sufficient data. 21 Ο. And what data are you referring to that came out after 2016? 22 There is a number of studies, including 2.3 Α. 24 some systematic reviews on, for example,

Page 230

prescription drug monitoring programs and how restricting the opioid supply directly led to people who had opioid use disorder transitioning to heroin use.

- Q. The 16 studies that you rely on in your -- in your report, all of them are dated 2015 or before. Correct? Sorry, 2016 or before.
- A. So in forming my conclusion, I also discuss in that section the PDMP studies that I just mentioned. But the 16 studies on nonmedical -- I'm sorry, prescription opioid use and heroin use, I haven't looked at the dates, but if you have looked and that is -- I would -- I would trust that you know the date.
- Q. One -- to be clear, one was dated 2016, and all of the rest are before. Does that sound right to you?
 - A. I haven't looked, but I -- I trust you.
- Q. And so -- so those studies would have been available to Compton at the time he wrote this paper, correct?
- A. Compton was writing about prescription opioid policies. None of those 16 studies dealt with prescription opioid policies. So those --

Page 231 those 16 studies wouldn't be a specific citation for that statement. Ο. Compton goes on in the next sentence to say, "heroin market forces, including increased accessibility, reduced price, and high purity of heroin appear to be major drivers of the recent increases in rates of heroin use." Do you see that? Α. T do. And does that conclusion apply to West 0. Virginia? Α. The conclusion that would apply to West Virginia here are that there are heroin market forces that have increased accessibility and reduced price, I believe. I would assume. And heroin market forces have increased the Ο. accessibility of heroin? Α. That's correct.

- 18
- 19 And then the increased accessibility is one 20 factor that leads to increased abuse?
 - Α. Of heroin?
- 22 Ο. Yes.

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- 23 Α. Yes.
 - Doctor Keyes, are you aware that the supply Q.

of prescription opioids in West Virginia has been reducing in the past five years?

A. Yes.

- Q. And your conclusion that you've stated in your report is that when there's an increase in supply of prescription opioids, that leads to an increased incidence of heroin use. Right?
 - A. I'm sorry, let me just read that again.

 Yes.
- Q. And so would you also expect that when there is a decline in prescription opioids in West Virginia, there would be a decline in the use of heroin?
- A. No. Not when there has been a systematic effort to create a population of people who have opioid use disorder and would be vulnerable to additional opioids being introduced into the market.
- Q. And that vulnerability is based on factors that would include the increased supply of heroin?
 - A. No. That --
- O. The --
- A. The vulnerability to heroin would not be the cause of the supply; it would be -- I'm sorry,

it would be the cause of the supply, not the result.

- Q. Well, but another cause would be an increase in the supply of heroin. That would be another factor that would lead to an increased use of heroin in West Virginia?
- A. I mean, as I said, I don't know of -- of people who take heroin, you know, randomly, right? You need some vulnerability factors. And the most significant vulnerability factor is access to prescription opioids.
- Q. There's also vulnerability factors in the West Virginia population that are individual and social and economic, correct?
 - A. That's correct.
- Q. And so those are also contributing causes to increases in the uses of heroin?
- A. I would say they all interact with the supply of prescription opioids.
 - O. And --

- A. The largest determinant of creating that vulnerability to addiction, to heroin addiction in particular.
 - Q. And then but in West Virginia, you see that

Page 234 there are a number of factors that contribute to 1 2 the use of heroin? 3 Α. Yes. MR. ARBITBLIT: Objection. 4 And that includes -- that includes, as one 5 Ο. factor, the increased supply of heroin? 6 7 To use heroin, you need access to heroin. 8 9 Q. And so as we spoke about before, the 10 increase in supply creates more availability and 11 creates more risk? 12 Α. Yes. That's true. And then individual and social factors are 13 Ο. also contributing causes to the use of heroin, 14 15 right? 16 I would say that they interact with opioid 17 access. Because with opioid use disorder, the one 18 necessary cause is access to an opioid. 19 You're aware in West Virginia there has 20 been a spike in the use of heroin? 21 Α. I'm generally aware. And there's also been a spike in the use of 22 Q. 23 fentanyl? 24 Α. Yes.

Q. During the time when prescription opioid levels have declined by about half?

MR. ARBITBLIT: Objection.

- A. The concurrent decline in prescription opioids that coincides with an increase in heroin use is not the comparison that is probably most apt; it is people who were using prescription opioids several years before.
- Q. No, but I just wanted to -- I understand you're making that point. I'm trying to ask just a factual point about West Virginia.
 - A. I see.

Q. Which is, there has been a decline of about 50 percent in the level of prescribing of opioids in West Virginia, correct?

MR. ARBITBLIT: Objection.

A. I'm not familiar with the 50 percent number. I would have to look at the distribution data on that specifically.

I know there has been a decline. But I'm not sure if it's been 50 percent. It would really depend on which medication we're talking about.

Q. Okay. I'll take you back later and we can

Page 236 look at some of that. 1 2 Α. Okay. 3 Q. Let me ask you to look at page 42 of your report, please. And at page 42, you say that - at 4 5 the next to the last paragraph on that page - you say, "In 2018 in Cabell County," "84% of" overdose 6 7 -- "overdose deaths were due to synthetic opioids." Do you see that? 8 9 Α. T do. 10 And that's -- and you compare it, to example -- for example, to "just 10% in 2013." 11 12 you see that? 13 Α. Yes. And do you have an understanding as to why 14 15 there has been this increase in the percentage of overdose deaths due to fentanyl? 16 17 Α. Yes. 18 And what's your understanding of it? Q. 19 As I said, I think that the population of people in West Virginia have had a longstanding 20 21 crisis with opioid use disorder that began with 22 what everyone recognizes as Phase 1 of the opioid 23 crisis, which is prescription opioid addiction, and 24 then people transitioned to heroin use disorder,

and that heroin market became adulterated with fentanyl, which is a highly potent synthetic opioid that is more likely to result in overdose.

Q. And so the adulteration, as we discussed before, that's being done by drug dealers?

MR. ARBITBLIT: Asked and answered.

- A. Yes, I think we can general -- it's being done in the sort of illicit marketplace.
- Q. And has there been, to your understanding, an increase in the fraction of heroin that is being adulterated with fentanyl?
- A. I'm -- I don't know that -- an answer to that.
- Q. And so if there were a higher fraction of adulterated heroin, that would be a contributor to the increase in fentanyl deaths, right?

MR. ARBITBLIT: Objection.

- A. I don't -- I don't know whether there's a higher fraction of adulterated heroin, but the availability of fentanyl will be correlated with fentanyl deaths.
 - O. Yeah.

A. So to the extent that the availability of fentanyl has increased, for example, via heroin,

Page 238 that would result in more fentanyl deaths. 1 2 I think that's where I would be in 3 agreement with your question. And you haven't measured the percentage of 4 Ο. 5 heroin that's being adulterated by fentanyl over time to figure out whether there's been a change in 6 7 that level -- that proportion of adulterated heroin? 8 9 Α. I'm not aware of data on that topic. 10 Are you aware of any people who take illicit fentanyl straight up, or is fentanyl, 11 12 illicit fentanyl, invariably taken as a form of 13 adulterated heroin? Fentanyl can be taken as a prescription 14 15 given to you by your doctor. So there are certainly people --16 17 Not illicit fentanyl, right? Ο. 18 Α. Not illicit fentanyl. Yeah. So I wanted to ask you about illicit 19 Q. fentanyl. 20 21 Α. Yes. You're aware of many people who take 22 23 illicit fentanyl straight up, or is it your 24 understanding that it's typically an adulterant in

Page 239 heroin? 1 Α. I believe there are people who take 3 fentanyl, illicit fentanyl, alone. Ο. 4 What percentage? But the majority of fentanyl use would be 5 fentanyl that is mixed with heroin. 6 7 Do you know what percentage of people in Cabell/Huntington are taking fentanyl by itself as 8 9 compared to an adulterant in heroin? 10 Α. I don't. No. 11 Do you have an understanding as to why drug Ο. 12 dealers in Cabell/Huntington are adulterating 13 heroin with fentanyl? 14 I believe as a cost-saving measure. 15 Ο. And why does it save costs? It makes the drug stronger with less 16 Α. heroin. 17 18 Ο. So it saves on the cost of heroin, and 19 fentanyl is relatively cheaper? 20 Right. You could give someone a smaller Α. 21 amount of heroin and mix it with fentanyl, and it would be as strong as a larger amount of heroin. 22 2.3 You don't have any studies that have looked 24 at transitions from heroin to fentanyl in West

Page 240 Virginia, do you? 1 2 Α. I don't. 3 Q. And do you have any studies that have looked at transitions from heroin to fentanyl across the U.S.? 5 I have seen literature on that topic. 6 Ι 7 haven't relied on that literature for this report, but just based on my own knowledge, there is 8 9 literature in that area. Actually from Maryland, I 10 believe. 11 Do you have -- do you have in mind any studies that show a direct transition from a 12 prescription opioid to fentanyl? 13 I would have to review those studies. 14 15 Ο. You don't have any in mind today? 16 Α. Today, I do not. Is there any published paper finding that 17 Ο. 18 prescription opioid misuse causes fentanyl deaths? 19 I quess I -- I think there's a -- quite a wide literature on -- on fentanyl deaths, and 20 21 fentanyl use, and drug use histories of people who 22 use these types of products. 23 Ο. I was --24 Α. So I think --

- Q. I was asking about ones that find causation between prescription opioid misuse and fentanyl deaths. I take it there's no study that finds that, is there?
- A. I believe there is in that prescription opioids, illicitly manufactured prescription opioids, can contain fentanyl, which would directly cause death. So that would be a direct causal relationship.
- Q. I was thinking of a study finding a causal relationship between the use of a legitimately-manufactured prescription opioid and a -- and fentanyl deaths. There's no -- there's no study finding that, is there?

MR. ARBITBLIT: Objection.

- A. No such study would be ethical. So no.
- Q. Let me ask you to look at page 41 of your report, please. And at the bottom of page 41 of your report, this is where you're talking about the number of people with OUD in Cabell/Huntington, right?
 - A. Yes.

Q. By the way, when you use the phrase "Cabell/Huntington community," on this page and

elsewhere in your report, what are you referring to? Is it the geographic area that embraces Cabell County and the City of Huntington?

A. That's correct.

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- Q. Okay. And you said that there's no systematic way to count the population of people with OUD in Cabell/Huntington; is that right?
 - A. That's right.
- Q. And you say at page 42 that in the middle of the page -- middle of that carryover paragraph at the top, you say, "The common linkage was history of nonmedical opioid use or dependent use of opioids." Do you see that?

You're trying to come up with an estimate of the OUD population in Cabell/Huntington and you say, "The common linkage was history of nonmedical opioids use."

- A. I'm just trying to find that sentence so I can see --
 - Q. Sorry.
 - A. -- where it -- where does it start?
- 22 Q. It starts with, "The common linkage" --
- A. Oh, I'm sorry. I see. I found it.
- Q. So -- so you're saying here that the common

- linkage among people in Cabell/Huntington who have OUD symptoms is that they engaged in nonmedical use of opioids?
- A. No. I'm -- the -- that sentence was about the Larney study, so in the Larney study, it includes different studies in the meta analysis, so the inclusion criteria include people who are in detox for OUD and other services for OUD, but the common linkage among the studies included in Larney is a history of nonmedical opioid use or dependent use of opioids, such as opioid use disorder.
- Q. So you come up here on pages 42 and 43 with an estimate of the percentage of the population in Cabell/Huntington that has OUD. Correct?
 - A. Yes. Yes.

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- Q. And what -- what -- what is your understanding of the more recent trends? You've done this analysis through 2018. Is that right?
 - A. Yes, through 2018.
- Q. Have you done any analysis of 2019 or into 2020?
- A. Well, from the CDC, only provisional data from 2019 has been released, so there's not available data yet for 2019 and 2020.

- Q. Let me ask you to look at your errata sheet which is Exhibit 104. And this is -- this first table is your Figure 13 which is, I think, your corrected figure from what appears on page 43.

 Right? Of your report.
 - A. Yes.

- Q. So we should -- we should rely on this corrected Figure 13 that's in Exhibit 104, right?
 - A. Yes.
- Q. Okay. And so you come up with a prevalence figure for opioid use disorder in West Virginia, Cabell County and nationally, right?
 - A. Yes.
- Q. And when you say "prevalence" here, it doesn't mean incidence in a given year; it means the prevalence over time of --
 - A. It means prevalence in that year.
- Q. In that year. So it would be looking at everybody who's got opioid use disorder in that year?
 - A. That's correct.
- Q. And so you could be -- in between years maybe to state the obvious you could have people who have opioid use disorder in both years and

Page 245 they're going to be counted in both of the figures, 1 2 right? 3 Α. In each data point. Right. Right. And so you don't know the 4 Ο. 5 percentage of people shown -- the percent -- I'm sorry, maybe --6 7 MR. HESTER: Let me strike that. Ο. It shows in Figure 13 for 2018 for Cabell 8 9 County 8.9 percent of the -- of the population has opioid use disorder? Is that correct? 10 11 Α. That's right. And is that 8.9 percent of the adult 12 Q. 13 population, total population? What is that? 14 That is the total population. 15 Ο. So it would include little babies as part 16 of your percentage? 17 Α. That's right. 18 Okay. And you're showing 4 percent OUD Q. 19 disorder in West Virginia, correct? 20 Α. Yes. For 2018. 21 Q. And 2 percent in the United States as a 22 whole? 23 Α. Yes. 24 Q. So you're coming up with an estimated OUD

rate for Cabell/Huntington that is more than twice the level of West Virginia?

A. That's right.

- Q. And have you evaluated the basis for the conclusion that the OUD rate in Cabell County/Huntington would be more than double the level of the State?
 - A. What do you mean, "the basis?"
- Q. Well, maybe I should back up. I take it in epidemiology, you don't just run numbers; you also try to figure out if they make sense. Right?
 - A. I do.
- Q. And did you figure out whether it made sense that the OUD rate in Cabell County/Huntington would be more than double the rate across West Virginia?
- A. Yes. I spoke to people on the ground in the Cabell/Huntington community as well as relied on the report of Todd Davies, which is cited in the report.
- Q. Okay. So let me just make sure I've got that. So you spoke to people on the ground, and then you looked at the expert report of Todd Davies?

- A. It was a -- I think a deposition that had some attachments to it that were reports from various -- to various -- reports that were generated for various purposes.
- Q. Who were the people you spoke to on the ground?
- A. I spoke to people from EMS; I spoke to people in the school community; I spoke to people in the fire department; I spoke to people in addiction services. Other government officials.
- Q. And did you keep notes of those discussions?
 - A. Yes.

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- Q. And were those notes included as materials you're relying on?
 - A. I don't know where the notes are at this point.
 - Q. You still have them?
- 19 A. Uh-huh. Yes.
 - Q. And did you type them up?
- 21 A. They were handwritten.
- Q. Keep them, if you could, please.
- And what did you ask the people in the
- 24 community?

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A. I spoke to people in the community about a wide range of topics. Mostly how the opioid crisis has affected people in the community. One thing I talked to them about was how many more people are living longer with OUD, though people are, fortunately, recovering from overdose -- so you've got a bigger proportion of people who have ongoing OUD.

In the schools, for example, there is a lot of problems with kids who have a lot of trauma due to parental drug use, and so we talked about that quite a bit.

And I also certainly said, you know,
I'm seeing - based on my estimates - that, you
know, for example, in 2018, upwards of 8-9 percent
of people in the Cabell/Huntington community might
have OUD; does that seem reasonable?

And by and large -- or across the board, people said "Yes."

Q. Aside from talking to people in the community, did you look at any structural factors that would explain an OUD level that's twice the level of the state? Did you look at any structural factors in Cabell/Huntington that would explain --

- A. Could you give me an example of a structural factor?
- Q. Well, maybe I can put it back to you.

 We've talked before about individual and social and
 economic factors that can be drivers of OUD,
 correct?
 - A. That's right.

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- Q. And those can all be causes that contribute to levels of OUD in a community?
 - A. Certainly.
- Q. And did you look at any factors whether individual, social, economic related to Cabell/Huntington to evaluate whether it made sense that the level of OUD was higher there than in other parts of West Virginia?
- A. I considered all of those factors in forming my opinion.
- Q. And what factors did you identify in Cabell/Huntington that, in your view, contributed to this high level of OUD?
- A. Well, I mean, the one thing that contributes to the high level of OUD is opioids. People don't -- cannot develop or maintain an opioid use disorder without opioid use, so that

certainly is front and center in my opinion.

But there is a lot of other issues in the Cabell/Huntington community as well that help maintain, you know, people in -- in addiction, including individual risk factors, financial insecurity, trauma.

You know, certainly people in the community who have addiction have a lot of other stressful life events.

- Q. And those are all contributors to the levels of OUD?
 - A. Sure, yeah, absolutely.
- Q. And did you -- did you look at any data suggesting that the level of prescription opioid use is different in Cabell County as compared to other parts of the state?
- A. I believe it's higher, based on my review of the literature.
- Q. And is that a -- when you say "higher," are you talking about the level of opioid misuse is higher in Cabell County?
- A. That -- opioid misuse is higher in Cabell -- or opioid use disorder, I should say, is higher in Cabell County based on my methodology. And I

Page 251 believe --1 2 Ο. And -- go ahead. 3 I believe prescription opioid use is higher as well. Is the level of prescription opioid misuse 5 Ο. higher in Cabell County than in other parts of the 6 7 state? Based on -- oh, prescription opioid misuse? Α. 8 9 I have not evaluated that. Do you have some reason to think that the 10 level of opioid misuse in Cabell County would be 11 higher than in other parts of the state? 12 13 I would imagine that it is given that the rate of OUD is twice as high than the rest of the 14 15 state. And the factors that would contribute to a 16 Ο. 17 higher level of opioid misuse in Cabell County 18 would include the ones you mentioned, the 19 individual, social and economic factors that would 20 contribute to a higher level of OUD -- of misuse 21 incidence? Well, again, and I think opioid use would 22 be the principle driver of opioid misuse. 23 certainly, other factors interact with opioid use, 24

and so again, these you know, other risk factors certainly would potentiate exposure to opioids.

- Q. And when you say "potentiate," you mean they would be contributing causes?
- A. Yes, they would interact with opioid exposure.
- Q. What I'm trying to get at is whether you have any evidence that the level of opioid use is higher in Cabell/Huntington than in other parts of the state?
 - A. I believe that it is.

- Q. And what's the basis for that?
- A. I believe there is data on shipments of opioids, for example. And when you look at overdose, for example, you know, that would all indicate a higher burden.
- Q. So you would see shipments as a proxy for use because the pills shipped would be then dispensed by pharmacies into the community?
- A. I would -- I'm not making a judgment about how the opioids are distributed in the community.
- Q. Well, there can't -- there can't be use unless they get to the community. So when -- so I'm trying to under --

- A. The pharmacy is one way that that would happen.
- Q. So I'm trying to understand, when you say you've seen relevant shipment data, you're assuming that the shipments then are dispensed by pharmacies into the community?
 - A. I'm not making that assumption.
 - Q. You don't know one way or the other?
- A. I think, as we've talked about, there are various ways that opioids that are shipped to a community would get into the community. One way is by walking into a pharmacy with a prescription, but there's other ways as well.
- Q. Going back to look at this -- this table, this -- sorry, Figure 13. So some percentage of the people with opioid use disorder are going to have misused illegally-trafficked drugs, right?
 - A. Yes.

- Q. And you don't know what that percentage is?
- A. Most of the people who've used illegally-trafficked drugs use medically as well.

 So I would say that given the strong overlap between illegal and legal use of opioids, I would say the majority of people with opioid use disorder

- based on available data have used illegal opioids and legal opioids.
- Q. So when you're -- when you're measuring opioid use disorder here, this is including people who are abusing heroin and have opioid use disorder from that source. Right?
 - A. That's right.

- Q. And it would include people who are abusing fentanyl and have opioid use disorder from that source?
- A. Only to the extent that it overlaps with other opioids.
- Q. Fentanyl -- I thought you said fentanyl was an opioid.
- A. Fentanyl is an opioid. But the Larney article that I relied on for forming the basis of this number, there were no studies in which there were fentanyl-only users or users of fentanyl that was laced with cocaine, for example, or another drug.
- Q. I see. The people who are reflected here, the percentage of people who are reflected as having opioid use disorder, would include people who have misused prescription opioids, right?

Page 255 Α. Yes. 1 2 Ο. Do you know what percent -- what the 3 percentage is of substance use disorders in the U.S. population? Any substance use disorder? 5 Q. 6 Yes. 7 Would you include nicotine dependence in that? 8 9 Q. We can do it either way. Would you -- I -- so including alcohol and 10 nicotine use disorders - which are the most 11 12 prevalent - I believe past year prevalence would be 13 about 30-35 percent. For -- and that would -- you would 14 15 characterize 35 percent --Yeah, that might be -- lifetime would be 16 30-35 percent. 17 18 So you would characterize in the U.S. population a lifetime substance use disorder in the 19 20 range of 35 percent? 21 I would imagine so. I -- for alcohol use disorders alone, it would be, I think, in the high 22 23 20 percents. And that's total population,

including the little babies. And so if you include

nicotine dependence in that as well, my opinion is you would probably get to 30 or 35 percent.

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- Q. So alcohol use -- so a substance use disorder based on alcohol, you would say, would be about 20 percent of the U.S. population?
- A. Probably more than 20 percent. Upwards of 30 percent.
- Q. And -- and substance use disorder based on tobacco, doesn't sound like you would put that as a high percentage then.
- A. How many people have nicotine dependence in the U.S.?
- Q. I was just trying to get to your number of 35 percent or so of the population having substance use --
- A. Well, that would be -- there's comorbidity, for example, between alcohol disorders and nicotine dependence. So you can't just add the two together, is what I'm saying.
- Q. I see what you mean. Okay. I'm learning the lingo. So when you say "comorbidity," that means people that might be using both at the same time.
 - A. That's right.

- Q. What percentage of the U.S. population, to your understanding, has a substance use disorder related to drugs?
- MR. ARBITBLIT: Objection. What drugs?
 - A. Yeah, I guess -- cannabis?

- Q. Any drugs. Cocaine, marijuana, heroin, misuse of prescription opioids. The whole gamut.
- A. So just to be very specific, I mean, cannabis is actually one that we might want to talk, because it is now legal in many states. So would you include that in terms of a drug use disorder?
- Q. Okay. Fair enough. What percentage of the U.S. population has a substance use disorder associated with cocaine?
 - A. I don't know that off the top of my head.
- Q. And what percentage of the U.S. population has a substance use disorder associated with methamphetamines?
- A. Again, for those specific drugs, I don't -- I don't -- I -- there is literature in that area, but I don't know it off the top of my head.
 - Q. But in the aggregate, your understanding is

Page 258 that there is a level of substance use disorder 1 2 across the population that's associated with a 3 number of drugs: Cocaine, methamphetamine and so forth. 5 Α. Yes. And that those numbers are ascertainable, I 6 Ο. 7 take it? I'm sorry? Say that again? Α. 8 9 Q. That --10 Α. Ascertainable, yes. 11 Ο. Yeah. 12 There are surveys. They are subject to 13 limitations. But there are regular surveys that are done in the United States on disorders like 14 15 cannabis use disorder and cocaine disorder and --16 Ο. Would you agree that the level of substance 17 use disorders associated with cocaine and 18 methamphetamine together is 10 percent or more in the U.S. population? 19 20 I don't want to speculate without having 21 the data. Let me ask you to look at page 45 of your 22 23 report, please. At the top of the page, I wanted 24 to ask you about an assumption. You say, "if 61%

of the 8,252 adults are parents" -- do you see that?

A. Yes.

- Q. What's your basis of concluding that 61 percent of that group of adults are parents --
- A. We used the estimate -- or I used the estimate of the Cabell County residents that are between 18 and 64, which is the general age that people use for parent -- for parenthood. That's been used in other studies.
- Q. Did you think to look at the census data on the percentage of households with children in Cabell County or in West Virginia?
- A. That could be on underestimate. Based on the work I've done in opioid simulation models, this is the way that other methodologies have done this, so I used a similar methodology.
- Q. But you didn't look at the census data to check whether it was consistent with 61 percent of the adults?
- A. I may have checked the census data. I'm not sure. I'd have to go back and look.
- Q. Let me ask you to look at page 15 of your report. This is where I wanted to ask you about

Page 260 the -- the recent trends in -- in West Virginia and 1 2 in Cabell County on levels of prescription opioids. 3 So in the paragraph immediately before heading B, you say that opioid prescriptions were 4 5 at 186 prescriptions per 100 persons as of 2011. Do you see that? 6 Yes. Α. And then you say that there's -- there's a 8 9 rate of 100 person -- I'm sorry, a rate of 92.1 10 prescriptions per 100 persons in the most recent year data available, 2018. Do you see that? 11 Yes. Just to note that the prescribing --12 Α. 13 the 186.6 prescriptions per 100 persons in 2011 was an increase from 175.3 in 2006, and then in 2018, 14 15 was 92.1 per 100 persons, just so --16 Q. Right. Right. And where did you get this 17 data? 18 The IQVIA data published by county by the CDC. 19 So it reflects -- just looking at these 20 numbers, it shows 186 prescriptions per 100 persons 21 as of 2011, right? 22 23 That's right. Α. And it shows a rate of 92.1 prescriptions 24 Q.

Page 261 per 100 persons as of 2018, right? 1 Α. Yes. 3 Q. So that's a 50 percent reduction in the level of prescriptions in Cabell County? 4 5 Approximately. Α. Q. Right. I mean, it's actually a little bit 6 7 more than 50 percent, right? Α. Right. 8 9 Q. And so -- and that's from 2011 to 2018? 10 Α. That's right. Do you know what the trend has been since 11 Ο. 12 2018? 13 Α. I do not. 14 And this is just counting numbers of 15 prescriptions, right? What do you mean by "numbers of 16 Α. 17 prescriptions"? 18 Well, in other words, it's not -- it's not 19 reflecting -- it's not reflecting the duration of 20 the prescriptions. It just reflects the number of 21 prescriptions written for prescription opioids, 22 right? 23 Α. That's right. And so -- so we don't know whether there 24 O.

was also a decline in the dose per prescription, do we?

MR. ARBITBLIT: Objection.

A. I believe those data are available. They're not cited in this paragraph.

- Q. Do you know what has led to this reduction in the level of prescriptions in Cabell County?
- A. I believe I would characterize it as multi-factorial.
- Q. And what are -- what are the factors when you characterize it as multi-factorial?
- A. Based on the evidence, there have been a number of policies that reduce inappropriate prescribing and other programmatic efforts to reduce the oversupply of opioids.
- Q. And what are some of the policies you have in mind?
- A. I believe there's data in West Virginia on their prescription drug monitoring program that I cite in this report which had kind of variable efficacy, but I think there were some parts of the prescription drug monitoring program that were effective in reducing the oversupply.
 - Q. There was also CDC quidance that we

Page 263 discussed before and other quidance? 1 2 Α. Yes. 3 Ο. Was there also guidance from the state of West Virginia? 4 I have not specifically evaluated guidance 5 from the state of West Virginia. 6 7 And you also understand, though - as you state here - that doctors are continuing to 8 9 prescribe opioids at the rate of "almost 1 10 prescription for every person in Cabell County," 11 correct? 12 Α. Yes. Yes. 13 And that reflects -- again, as we've discussed, that reflects doctors' judgments that 14 15 are being made in 2018 about --I think that would be a simplistic --16 Α. 17 MR. ARBITBLIT: Objection, asked and 18 answered. 19 The -- let's look up higher on the page. 20 There is also a reference to the "MME per person in 21 West Virginia." Do you see that? It's at the 22 paragraph at the end of the paragraph above the one we were just looking at. 23 24 Α. Yes.

- Q. You don't state those data for Cabell County. Did you only have those data available for West Virginia?
- A. I believe that the paper that I cite in this paragraph reported at the state level.
 - Q. Did you look at the county level?
- A. I did, in the next paragraph that we've discussed.
- Q. Well, but the next paragraph is dealing with numbers of prescriptions, whereas this paragraph above is dealing with MME per person.
- A. I see. No, I have not looked at the MME per person in Cabell.
- Q. Do you know that the MME per person has declined in Cabell County?
 - A. I have not seen that data.
- Q. I take it that the figures you cite here reflect a decline in MME per person of prescription opioids in West Virginia statewide?
 - A. That's right.

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- Q. And have you seen more recent data on that trend in reductions in MME per person?
 - A. I have not.
 - Q. There's -- let me ask you to look at page

Page 265 40, please, of your report. At the very top of the 1 2 page, you say - first full sentence - "With that 3 caveat, available evidence indicates that non-medical pain reliever use (which is primarily 4 5 opioids) is declining among non-institutionalized mostly household populations in West Virginia 6 7 overall." Do you see that? 8 9 Α. T do. 10 Ο. What's the basis for your statement there 11 that the nonmedical pain reliever use is declining? 12 Α. These are based on the NSDUH data. 13 And did the NSDUH data collect nonmedical Ο. pain reliever use? 14 15 Α. Yes. 16 Ο. And so -- so this reflects two percentages 17 you report. You report a percentage of 1.20 18 percent to .9 percent. Do you see that? 19 T do. Α. 20 What does 1.20 percent in that sentence 21 refer to? Are you saying percentage of households 22 in West Virginia that are engaged in nonmedical 23 pain reliever use? That is the percentage of the NSDUH sample, 24 Α.

- which is noninstitutionalized, mostly households, so generally much lower risk than the general population.
- Q. But it -- so it's -- when we say "noninstitutionalized household population," that means people who aren't in prison or in a mental facility?
 - A. Substance use treatment, for example.
 - Q. Okay.

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- A. Your highest risk populations are not included in that.
- Q. Okay. So -- I understand what you're saying. So it's looking at the population that's not in substance abuse treatment, in prison, in a mental facility. And among that population, that's the population that they were referring to as the noninstitutionalized mostly household population?
 - A. Yes.
- Q. What does "mostly household population" refer to?
- A. I believe that there are some nonhouseholds that are included in the NSDUH sampling frame. And I would need to go back to the methodology. But, for example, I think that they do attempt to go to

college dormitories and some other kind of group quarters.

- Q. So children in college are considered outside the mostly household population, or they are in?
- A. I would have to check the methodology to be sure because it's changed somewhat over time. But the reason I said "mostly household" is because I do believe there are some group quarters that are included in this -- attempt to be included in the sampling frame.
- Q. So when we say "1.2 percent," we're saying of that population, 1.2 percent reported past month nonmedical pain reliever use?
 - A. That's right.

- Q. And nonmedical pain reliever use would include things other than opioids?
- A. Typically that estimate from the NSDUH is

 -- is interpreted as opioid -- nonmedicine

 prescription opioid use disorder. The examples

 that are given are opioids, I believe.
- Q. So if we look at this -- this data, it shows us in 2015-2016, 1.2 percent of this population the noninstitutionalized population -

Page 268 1.2 percent reported nonmedical use in the prior 1 2 month? 3 Α. That's right. And then that dropped to .9 percent in 4 Ο. 5 2017-18 for that same population? That's right. 6 Α. 7 And do you have an understanding of what the reason is for the drop in the nonmedical use? 8 9 Α. No. I'm not sure with that particular population why that --10 11 I mean, a change from 1.2 to .9 is not 12 that substantial of a change. It could be sampling 13 error. And so another way to put this is that in 14 15 2017-2018, 99 percent of this population did not report nonmedical use in the last month? 16 17 Α. The sample, yes. 18 Let me ask you to look at page 26 of your Q. And at the bottom of the page, the last 19 paragraph, you say that "More recent data generally 20 21 show that the prevalence of non-medical prescription opioid use is stabilizing or beginning 22 to decline." 23 24 Do you see that?

- A. It says "depending on the population and the outcome."
 - Q. Right.

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- A. "And that the burden remains substantial."
- Q. Right. Totally fair. Totally fair. And that's the whole sentence. I wasn't cutting it off. I wanted to just focus you on the fact "that the prevalence of nonmedical prescription opioid use is stabilizing or beginning to decline."

What's your basis for that?

- A. That, I used the NSDUH data for that statement. Yeah, I used the NSDUH data.
- Q. Now, this NSDUH data that you report only shows through 2013, right?
 - A. That's correct.
 - Q. Is there more recent data available?
- 17 A. Yes.
 - Q. And did you look at that more recent data?
 - A. In this paragraph, I did not include the more recent data. But it could be updated to be more recent.
 - Q. Do you know what the data reflect?
 - A. Off the top of my head, I do not.
 - Q. When you say that data from NSDUH indicate

Page 270 that among those 18 through 64, prevalence of 1 2 nonmedical prescription opioid use decreased from 3 5.4 percent in 2003 to 4.9 percent in 2013, when you refer to 18 through 64, is that the entire 5 population, or is that the noninstitutionalized population again? 6 Noninstitutionalized. As NSDUH doesn't include institutionalized Ο. 8 9 in its study --10 Α. That's right. 11 -- or its sampling. And so this -- this Ο. number is higher than the figure you showed on page 12 13 40. On page 40, you showed a decline from 1.2 percent to .9 percent, whereas here on page 26, you 14 15 report 5.4 to 4.9. Now, I know those are different 16 years, but are you reporting some different 17 population in those two figures? 18 I would imagine that these are different 19 outcomes: Past month use versus past year uses 20 versus lifetime use. All of those would be 21 different. 22 Ο. Oh, so --

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A. The higher prevalence, it's either past year or lifetime.

- Q. Okay. So this is looking at a different measurement than the measurement on page 40 which is prior month use.
 - A. That's right.
 - Q. All right.

MR. HESTER: Okay. Why don't we take a quick break, if we can, maybe ten minutes or so? Can we come back at 4:00?

9 VIDEO OPERATOR: Going off the record.

10 The time is 3:52 p.m.

(A recess was taken after which the proceedings continued as follows:)

VIDEO OPERATOR: Now begins Media Unit 7 in the deposition of Katherine Keyes. We're back on the record. The time is 4:01 p.m.

BY MR. HESTER:

- Q. Doctor Keyes, let me go back quickly to your errata sheet. And we're talking about Figure 13.
 - A. Okay.
- Q. And so in this figure, the 8.9 percent of the population in Cabell County that you've estimated as having opioid use disorder, that -- that includes people who have engaged in misuse of

Page 272 prescription opioids, right? Α. Yes. Q. And some of the people who have engaged in misuse of prescription opioids at one time or another had a legitimate prescription for opioids, right? Α. Correct. But at the time they were engaged in misuse of opioids, that's not a legitimate medical use, correct? MR. ARBITBLIT: Objection. They might be legitimately medically using Α. as well, but typically, the definition of "misuse" includes outside of a doctor's prescription. So the way -- the way you've used misuse in

- Q. So the way -- the way you've used misuse in your report is people who are using opioids outside the scope of a doctor's prescription?
 - A. Yeah. Yes.

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Q. And so for any -- any particular person who's engaged in misuse, if they had a legitimate prescription at one time but they're engaged in misuse later, when you talk about misuse, are you talking about the time in which they were engaged in misuse or the prior time when they were engaged

Page 273 in legitimate use? 1 2 MR. ARBITBLIT: Objection. 3 Α. You can -- people can have a legitimate prescription and concurrently be misusing. 4 don't think I would differentiate those two time 5 scales the way that you have. 6 7 And when they're concurrently misusing prescription opioids, the pills that they're 8 9 misusing are not covered by a legitimate prescription, right? 10 11 The -- sorry. The misuse definition would be outside of -- so taking more than the doctor 12 13 prescribed or without a prescription. So the pills that they're misusing are not 14 15 ones that would be covered by a legitimate prescription? 16 17 Α. That's right. Let me ask you to turn to page 29 of your 18 Q. report, please. And at the bottom of the page, you 19 say that "The supply of opioids was also 20 21 facilitated by pharmaceutical promotional activity to physicians." 22 23 Do you see that? 24 Α. I do.

Q. And when you talk about "pharmaceutical promotional activity to physicians," you're talking about activity by pharmaceutical companies; is that right?

MR. ARBITBLIT: Objection.

- A. This particular sentence refers to pharmaceutical companies, but there's other marketing activities as well. It doesn't preclude other kinds of marketing activities.
- Q. But here in your report, in this sentence and in this paragraph, you're talking about promotional activity by pharmaceutical companies?
- A. I'm just not aware -- I think for the most part, the studies that I talk about in this section refer to marketing activities from pharmaceutical companies.
- Q. And those would also be referred to as manufacturers of pharmaceuticals?
 - A. That's right.
 - Q. Not distributors, correct?
- A. I'm aware that distributors also engaged in opioid marketing. So I don't preclude that from occurring or contributing to oversupply. But in these sections, I believe I'm referring to

specifically monetary value paid to physicians for opioid products, which I believe are a majority of pharmaceutical companies, manufacturing companies.

- Q. So the activities that you're discussing in this paragraph from 29 over to 30, that's dealing with activities engaged in by manufacturers.
 - A. I believe so.

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- Q. And the reference -- you're talking, in particular, on this paragraph on 29 and 30, you're talking about outreach by pharmaceutical companies to doctors, correct?
- A. I'm referring to payments to physicians for -- with regard to opioid products. And so it could include outreach, but also includes other types of marketing activities.
 - Q. Okay.
 - A. For example --
- Q. But my point is that insofar as somebody's reaching out directly to doctors, that's activity engaged in by manufacturers, correct?
- A. In this section. There may be other activities that distributors did to reach out to doctors. I'm evaluating the specific information that's in this open payments database.

- Q. Are you aware of -- of any activities engaged in by distributors to reach to doctors about the risks and benefits of particular drugs?
- A. I know that the distributors engaged in marketing activities with regard to opioid products. But I'm not -- I haven't evaluated the specifics of those marketing activities.
- Q. So you're not familiar with what distributors have done in relation to promoting --
- A. I'm generally familiar, but I'm not aware of specific outreaches to doctors.
 - O. And --

- A. It could have occurred. I just don't know -- I'm not aware of it.
- Q. And is your understanding that the outreach to doctors about the risks and benefits of particular drugs is something that's engaged in by manufacturers?
- MR. ARBITBLIT: Objection, misstates the record and the testimony.
- A. Yeah, I'm not -- I am specifically in this paragraph talking about a particular data source, this open payments database, which I believe catalogs primarily pharmaceutical manufacturer

Page 277 marketing, but I don't preclude other types of 1 2 marketing to physicians. 3 Q. But I was asking you a different question. All right, I'm sorry, I'm not understanding 5 the question. Are you -- are you aware that manufacturers 6 Ο. are the ones who reach out to doctors with -- to 7 describe the risks and the benefits of particular 8 9 drug products? 10 MR. ARBITBLIT: Objection, vaque. I'm not aware that manufacturers would be 11 12 the only ones who would reach out --13 I didn't ask if they were the only ones. Q. Ι said are you aware --14 15 Α. Oh -- I ---- if manufacturers reach out to doctors to 16 Ο. 17 describe the risks and the attributes of drug 18 products? 19 MR. ARBITBLIT: Objection to the prelude. And "The ones" was part of your last 20 21 question, so it did --22 MR. HESTER: Oh, okay. Dan you're 23 really -- you're engaged in speaking objections

now, and you're coaching the witness. Now, please.

Page 278 I think you can state -- you can state your 1 2 objection to form, and then we'll go on. 3 MR. ARBITBLIT: And it's Don, not Dan. And you're misleading the witness. 4 5 MR. HESTER: Don. Sorry, Don. MR. ARBITBLIT: You're 6 7 mischaracterizing your previous question. That's misleading. 8 9 MR. HESTER: State the objection to 10 form and then me go on, please. 11 MR. ARBITBLIT: Objection to form. 12 MR. HESTER: You're going beyond what you're entitled to be doing. 1.3 14 MR. ARBITBLIT: Object to form. 15 Please qo on. 16 BY MR. HESTER: 17 So I wanted to ask one question, which is: Ο. 18 You're aware that manufacturers engage in outreach to doctors to describe the risks and benefits of 19 particular drugs? 20 21 Α. Yes. Do you have any evidence or information 22 that distributors reach out to doctors directly to 23 24 describe the risks and the attributes of drugs?

MR. ARBITBLIT: Objection.

- A. I am aware that distributors engage in opioid marketing in general, and I don't preclude that from occurring. But I'm -- that's not what I evaluate in my report, and I don't offer an opinion on it.
- Q. And so -- and are you aware of activity by distributors to reach out to doctors to describe the risks and the attributes of prescription opioids?
- A. I haven't evaluated any information on that, so no, I'm not aware of that.
- Q. And when you talk about promotional activity by distributors in a couple of your answers, Doctor Keyes, are you referring to promotional activity involving outreach by distributors to pharmacies?
- A. I believe that's part of the marketing activities of the distributors.
- Q. Let me ask you to look at page 14 of your report, please. At the -- at the bottom of page 14, you say, "The increase in opioid prescribing was driven by a multitude of factors, including direct marketing to physician using data that

understated opioid use disorder risk in patients."

Do you see that?

A. I do.

- Q. And there you're talking about direct marketing to physicians, and the reference you're making there is to direct marketing to physicians by manufacturers; is that right?
- A. I don't specify who's doing the direct marketing. So any direct marketing that occurred to doctors that underestimated opioid use disorder risks would be included in that statement, regardless of who did the marketing.
- Q. But the -- I -- so is it your understanding that the direct marketing to physicians using data that underestimated opioid use disorder risks, was that done by manufacturers?
- A. I am aware of marketing that was done by manufacturers, and there may have been other marketing by other companies as well.
- Q. What you're specifically discussing in your report is direct marketing by manufacturers to physicians?
- A. No. I would say that I'm specifically talking about direct marketing by whomever did the

Page 281 marketing. 1 Q. Do you know of any direct marketing by 3 anyone other than manufacturers? I know of direct marketing by 4 5 manufacturers, and I have reviewed some material related to marketing from other companies as well. 6 I don't preclude there being direct marketing to physicians. I haven't evaluated all the marketing 8 9 materials. O. And I'll --10 11 MR. ARBITBLIT: I'm -- I just need to 12 interpose an objection, Tim, that this is subject 13 matter that's been gone over and you're not asking any questions about a West Virginia nexus. 14 15 That's my objection. It's based on our previous discussion with the special master. 16 17 MR. HESTER: I wasn't aware -- I 18 wasn't aware that there had been prior questioning 19 on this. I mean -- I wasn't aware -- I wasn't aware that that was true, Don. Is that --20 21 Do you say -- are you telling me 22 there's been prior questioning on -- on these 23 marketing issues in New York or in Ohio? 2.4 MR. ARBITBLIT: Yes.

Page 282 MR. HESTER: I wasn't aware of it. 1 2 MR. ARBITBLIT: I appreciate your 3 honesty. BY MR. HESTER: Are you aware of any direct marketing to 5 physicians by distributors in West Virginia? 6 I haven't evaluated that. So no, I'm not aware. 8 9 Q. Are you aware of any direct marketing to physicians by distributors in Cabell or Huntington? 10 The same answer. I haven't evaluated any 11 material related to that, so I'm not aware of it. 12 13 Are you aware -- what -- you had mentioned Q. before marketing activities by distributors. 14 15 you aware of any marketing activities by distributors to any pharmacies in West Virginia? 16 I believe that that's been detailed in 17 Α. 18 other reports. I -- from my understanding, is that 19 the distributors do market to pharmacies and do 20 market opioids. So I'm generally aware that that 21 occurs. 22 Ο. And you're basing that on other expert 23 reports? 24 Α. And the materials therein, yes.

Q. Have you -- have you yourself looked at those issues of marketing to pharmacies by distributors in West Virginia?

MR. ARBITBLIT: Objection.

- A. Not beyond what I've read.
- Q. What you've read in other expert reports?
- A. And the materials therein.
 - Q. In those other expert reports, you mean?
 - A. That's correct.
- Q. Are you aware that information on the risks and benefits of prescription opioids was conveyed to doctors in West Virginia by drug manufacturers?
 - A. Yes.

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- Q. And what's your -- what's your understanding of that?
 - A. My understanding of it is that manufacturers understated the risks and overstated the benefits.
 - Q. And have you seen indications that this occurred in West Virginia?
 - A. I believe that there are materials related to that, the Van Zee article, I think, in particular, talks about the West Virginia area.
 - Q. So the materials that you have seen on

marketing related to descriptions of the risks and benefits to doctors in West Virginia, that involves materials disseminated or promoted by manufacturers?

- A. Generally, the materials that I have seen on marketing to physicians has been -- has been with regard to manufacturers. Although again, I don't preclude any other types of companies from marketing opioids.
- Q. But the only ones you've seen have involved materials developed or used by manufacturers?
- A. In general, yes. But I've reviewed other material that indicates that there's other kinds of marketing activities as well.
- Q. Let me -- let me ask you to turn to page 53 of your report. And this is where you discuss mortality rates from prescription NSAIDS, right?
 - A. As compared to opioids, yes.
 - Q. And what are prescription NSAIDS?
- A. Nonsteroidal anti-inflammatories, in general. And they're a prescription medication that is another medication that's used for pain relief.
 - Q. And do you have an understanding that

- NSAIDS are used as a form of pain treatment in West Virginia?
 - A. I would have no reason to think that they are not used in West Virginia.
- Q. And do you believe that the statements here on NSAIDS that you lay out apply to the population of West Virginia?
 - A. I would imagine so.

- Q. So you state here a mortality rate among prescription NSAID users of "47 per 1000 patient years." Is that right?
- Sorry, it's in the middle of the page.

 It's about six lines up from the bottom of the page.
 - A. Yes, I see that. The "mortality rate among opioid users is 75 per" 100,000 and among NSAID users is "47 per" 100,000 -- I mean, per thousand.
 - Q. Right. So both of them are per thousand, right? So you found the mortality among opioid users of 75 per 1000 patient years and 47 per 1000 patient years among prescription NSAID users. Is that right?
 - A. That's right.
 - Q. And those statistics, in your view, are

applicable to the West Virginia population?

A. Yes.

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- Q. And the reference to opioid users would include opioid misusers or people engaged in opioid misuse?
- A. I think this is Medicare beneficiaries who are prescribed opioids.
 - Q. But would it also --
 - A. Or -- they were all medical users.
 - Q. But they could also be nonmedical users?

 MR. ARBITBLIT: Objection.
- Q. I'm trying to understand what you're saying. Doctor, can you --
- A. In addition to medical use, they could also use nonmedically.
- Q. Right. So the statistic you cite here which you indicated applies to West Virginia could include opioid users who are using them nonmedically?
- A. The NSAID number could include opioid users who are using nonmedically as well. The comparison is medical users to medical users. Certainly there could be nonmedical users in both groups as well.
 - Q. The -- are you aware of any meaningful

level of nonmedical use prescription NSAIDS in West Virginia?

- A. No, I'm saying the NSAID users could be using prescription opioids nonmedically.
- Q. Well, let's just first focus on the mortality rate you cite for opioid users. That mortality rate could include people who are engaged in opioid misuse as well as people who have a legitimate prescription, correct?
 - A. That's correct.

MR. ARBITBLIT: Object.

- Q. And the -- the level of death rate you show for prescription NSAID users in West Virginia, what are the factors that contribute to prescription NSAID deaths in West Virginia?
- A. Can we pull out the study and take a look at it? And we can see exactly what they have in the study.
- Q. Yeah. I can't promise you I've got that one, actually. I'll see. Let me see if I've got it.
- A. I just don't want to mischaracterize what the authors wrote.
 - Q. Let me see if I've got that one.

Page 288 Yes, it's Exhibit 96. 1 2 KEYES DEPOSITION EXHIBIT NO. 96 ("The Comparative Safety of Analgesics 3 in Older Adults With Arthritis" by 4 5 Solomon, et al. dated Dec. 13/27, 2010 was marked for identification purposes 6 7 as Keyes Deposition Exhibit No. 96.) And so again the question is, what factors Α. 8 9 contributed to NSAID mortality? 10 Q. Yes. 11 I don't know that they -- the study 12 describes mortality. Let's see. 13 I don't think it describes the specific causes of deaths for the mortality events unless 14 15 I'm overlooking that. 16 Ο. Do you have reason to believe the mortality 17 rate arising out of NSAID use would be any higher 18 in West Virginia, given the population? 19 It's possible. There's more -- as we've talked about, there's an increased level of 20 21 indications for which pain could be a contributing factor. 22 2.3 Have you looked at that, whether the level Ο. 24 of NSAID mortality in West Virginia is higher than

Page 289 for the country as a whole? 1 2 Α. I have not. 3 Q. Let me ask you, please, to look at Exhibit 108. 4 KEYES DEPOSITION EXHIBIT NO. 108 5 ("Prescription opioid use disorder and 6 7 heroin use among youth nonmedical prescription opioid users from 2002 to 8 9 2014" by Martins, et al. dated 2-1-18 10 was marked for identification purposes 11 as Keyes Deposition Exhibit No. 108.) That's going to be one of the ones that was 12 Α. 13 sent --Yeah. Oh, yea, sorry. It probably was one 14 Ο. 15 that was just sent. Α. 16 That's okay. 17 Do you have it there? Ο. 18 Α. I do. 19 So Exhibit 108 is a paper written by Silvia 20 Martins and others, including Doctor Keyes, 21 entitled "Prescription opioid use disorder and 22 heroin use among youth nonmedical prescription opioid users from 2002 to 2014." 23 24 Doctor Keyes, I take it you're familiar

with this paper.

- A. Yes.
- Q. Let me ask you -- let me ask you to look at page 7. And I wanted to ask you about the first full paragraph on the page where it says, "Although our study does not assess underlying causes, the increasing trend in prescription opioid use disorder observed in young adults might be at least partially explained by historical factors described elsewhere in the literature."

Do you see that?

- A. Yes.
- Q. And I wanted to ask you: When you refer to "historical factors described elsewhere in the literature," you're referring to other papers that had previously identified these as factors that might be contributing to prescription opioid use disorder?
 - A. Yes.
- Q. And let me ask you -- I want to -- I want to go through these ones that you list here and ask if they apply to West Virginia, to your understanding. The first one listed is "a shift in medical practice of prescribing opioids from

Page 291 end-of-life pain and cancer to chronic non-cancer 1 2 pain, particularly in young adults." 3 Do you see that? Α. T do. 4 And is that a factor that you would see as 5 contributing to increases in opioid use disorder in 6 7 West Virginia? Α. Yes. 8 9 Q. The next one is "an increased rate of 10 opioid prescription by physicians due to a higher sensitivity to patient's pain." Is that a factor 11 12 you'd see as applying to an increasing trend in prescription opioid use disorder in West Virginia? 1.3 Α. Yes. 14 15 Next one is "the endorsement of pain as a 16 'fifth vital sign' by the Joint Commission with a controverted pain metric." Do you see that? 17 18 Α. I do. Is that a factor that you would see as 19 contributing to the increasing trend in opioid use 20 21 disorder in West Virginia? 22 Α. Yes. 23 What do you mean there by "controverted

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pain metric?"

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- A. I'll have to go to that Franklin article, because I'm not exactly sure what "controverted" means in that context.
- Q. I can tell you I'm not that well prepared. I don't have that one handy, so we can keep going.

The next one is "an increased distribution of opioids by the pharmaceutical industry and creation of an opioid rich environment." That's what we've been discussing today, correct?

- A. Part of what we've been discussing today.
- Q. Right. The next one is "state lobbying by pain advocates for prescription opioid use."

Do you see that as a factor that contributed to the increasing trend for prescription opioid use disorder in West Virginia?

- A. Yes.
- Q. Do you see a reference to "'doctor shopping' by patients"?
- A. Yes.

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- Q. Is that a factor that contributed to the increasing trend to prescription opioid use disorder in West Virginia?
 - A. Yes.

- Q. Do you see the reference "physician sensitivity to pain exploitation by opioid users"?
 - A. Yes.

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- Q. What does that mean?
- A. I think that generally means patients who overstate their medical need for opioids in order to obtain the medication from physicians.
- Q. So that would be something that you would see as contributing to the increase in trend in prescription opioid use disorder in West Virginia?
 - A. Yes.
- Q. And then there's a reference to "overprescribing," "which leaves excess medications available for misuse or redistribution by a nonmedical-sanctioned venues." Do you see that?
 - A. Yes.
- Q. And that's a factor that you see as contributing to the increasing trend of prescription opioid use disorder in West Virginia?
 - A. Yes.
- Q. And the overprescribing there is overprescribing by doctors and the medical community, correct?
 - A. When we're talking about prescribing, yes,

that would -- that would refer to the people who are prescribing, the doctors.

- Q. Doctor Keyes, do you agree that the opioid crisis in Huntington/Cabell is caused, at least in part, by criminal drug trafficking organizations?
- A. I'm sorry, I'm just going to read the question.

I think that drug trafficking contributes to opioid-related harms, yes.

Q. And do you believe that people who leave prescriptions lying around in their medicine cabinet where teenagers or others can easily take them contributed to opioid-related harms in Cabell/Huntington?

MR. ARBITBLIT: Objection, argumentative.

A. They had to get the opioids to begin with, so you know, to the extent that there are opioids that are oversupplied and end up in people's homes that can then be distributed nonmedically, sure.

You know, again, availability - kind of what we talk about in this paper, an opioid rich environment due to excess supply of opioids - contributes, and the way in which that excess

supply gets funneled into the community, one of those routes is prescriptions sitting around in people's cabinets.

- Q. Do you agree that the actions of the DEA in increasing the quotas for prescription opioids contributed, in part, to the opioid crisis in Cabell/Huntington?
- MR. ARBITBLIT: Objection, asked and answered.
- A. Yes. I think anything that increases the supply. All of the suppliers. So if something contributed to the increase in the supply, then it contributed to the increase in harm.
- Q. Do you have an understanding that medical insurers encouraged the use of prescription opioids over other alternatives for the treatment of pain?

 MR. ARBITBLIT: Objection.
- A. I'm not aware of specific material related to specific insurers. I do know that rates of prescription do correlate with what are on the formularies for different insurance companies.

 That's been documented in the literature.
- Q. And do you have an understanding that the policies of insurers contribute to the supply of

opioids in West Virginia?

- A. To the -- yes, to the extent that they made opioids more available.
- Q. Do you have an understanding that pharmacy benefit managers, with their formulary policies, contributed to the expansion of the supply of opioids in West Virginia?
- A. I have not evaluated any literature on that topic.
- Q. Do you have an understanding one way or the other that the West Virginia Board of Medicine was slow in revoking licenses or otherwise shutting down doctors who were engaged in overprescribing?
- A. Again, I have not seen any literature that's associated that practice with opioid prescribing.
- Q. Do you have an understanding that the West Virginia Board of Pharmacy was slow in revoking licenses of certain pharmacies and thereby contributed to the supply of opioids in West Virginia?
- A. I have not evaluated any literature with regard to that.
 - Q. Let me ask you to turn to page 46 of your

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Page 297 report, please. Do you have any expertise 1 2 yourself, Doctor Keyes, in addiction -- addiction 3 abatement or treatment programs? I generally have expertise in -- in 4 5 studying the effectiveness of abatement and treatment programs. 6 7 So that's -- that's something you engage in Ο. through reviewing epidemiological studies? 8 9 Α. For example, yes. 10 Ο. And --11 And I've participated in treatment studies as well. 12 13 Have you -- have you been involved in Q. designing treatment studies? 14 15 Generally, yeah, as an epidemiological 16 study design consultant, yeah. 17 Where have you done that? Ο. 18 Α. At Columbia. 19 And for what communities? Q. 20 Most specifically communities in New York. Α. 21 Ο. Have you been engaged in any of the design 22 around abatement programs or treatment programs for Cabell/Huntington? 23 24 Α. No. I have reviewed literature.

- Q. Let me ask you to look at page 41, please. And I wanted to ask you, at the end of the first full paragraph on that page, you refer to a dis -- your discussions with local officials and experts about needs for the community?
- A. Yes.

- Q. What -- can you tell me about these discussions with local officials and experts? Who were they?
- A. My -- I have listed their names here. I can read -- I can read you their names.
- Q. Okay. The people -- the people you spoke to are the ones who are listed in that paragraph?
 - A. That's right.
- Q. Are there others you spoke to aside from these folks?
- A. There are others that I list in other sections of the report. But the people that I spoke with are listed in the report.
- Q. And in relation to this particular issue, the people you spoke with are the ones who are listed here on these -- on these needs for the community?
 - A. That's right.

Page 299 Did you keep notes of those discussions? 1 0. 2 Α. I did. 3 Q. And are those handwritten notes? Α. That's right. 4 You still have them? 5 Q. Α. 6 Yes. 7 Okay. I would ask you to keep those too, 0. and we'll pursue that afterwards. 8 9 Α. Sure. Doctor Keyes, I take it you have not 10 0. yourself been to Cabell County or the City of 11 Huntington? 12 13 Α. I have been to --Ο. You have? 14 15 -- both Cabell County and the City of 16 Huntington. 17 Oh, because you've met with these folks. Ο. I did. 18 Α. 19 That's where you had the meetings? Q. 20 Α. Yes. 21 Q. Are you -- do you have expertise in the laws and regulations governing the distribution of 22 controlled substances? 23 24 I've generally reviewed epidemiological Α.

literature with regard to opioid policy. So to the extent that the policies have been evaluated in the epidemiological literature, I have expertise in that.

- Q. Do you have any particular expertise on suspicious order monitoring activities?
 - A. I do not.
- Q. Have you reviewed any of the orders that were submitted by pharmacies in Cabell/Huntington for prescription opioids?
 - A. No.

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- Q. Have you reviewed any of the diligence files or investigative documents prepared by distributors with respect to customers in Cabell/Huntington?
 - A. I have not.
- Q. Just looking here at my notes, Doctor Keyes. I may be done.

Doctor Keyes, I take it you -- that you have not focused your opinions on any of the individual specific distributors who are defendants in this case?

A. My opinions apply to all of the distributors in the case.

- Q. But you've not reviewed specific documents related to their individual activities?
 - A. Generally, no.
 - Q. Okay.

MR. HESTER: I think that's all I have, so I will pass -- pass you along to my colleagues. Thank you, Doctor Keyes.

THE DEPONENT: Thank you very much.

MR. ARBITBLIT: So to the extent others plan on inquiring, the protocol requires a video feed, which we don't see. Perhaps you have video feed that's not turned on, but to the extent that there is no video feed, we would object that that's not permitted under the protocol.

MR. METZ: I've had my video off for most of the day, but it's on now.

MR. HESTER: Actually, before you start, Carl, I do -- I did want to state one thing for the record -- and I know that we have a difference of agreement, but -- difference of view on this point.

But we -- we have been surprised today by the position taken by the plaintiffs that we could not inquire fully into all aspects of Doctor

Keyes' West Virginia report. We had understood it was a stand-alone report and we could inquire into it fully.

I understand the ruling by Judge
Wilkes, and we undertook as best we could to comply
with it during the day. But I did want to state
our objection that we continue to believe that we
should have been permitted to inquire fully into
this report without -- without limitation based on
examination on other reports in other
jurisdictions, and we have not been able to pursue
some lines of inquiry that we have -- we had
intended to pursue today with Doctor Keyes.

Doctor Keyes, it's no fault of yours, but there's a ruling that was made today that we believe has prejudiced us in relation to our ability to take a full and complete deposition today.

MR. ARBITBLIT: And I'll just state briefly for the record that I feel Special Master Wilkes addressed the lack of surprise due to the previous rulings of the Court and that we addressed it with Rule 26 and that his ruling was fair and that we have generally been very accommodating with

your questions, and you have covered a lot of ground with articles and subject matter that was the subject of previous depositions, to which we have not objected because you were careful to relate it to West Virginia, which is appropriate under the special master's ruling.

So we don't think there's been any surprise, nor any prejudice, nor any reason to be concerned about today's proceedings.

MR. HESTER: And just to -- just to follow up very briefly, my point - which I did want to preserve - is that I forewent lines of inquiry I had planned on today that related to Doctor Keyes' West Virginia report, and I had not anticipated that we would be precluded by reports submitted in separate litigation and other jurisdictions, and you know, I understand we have a difference of view on this, and I understand that Judge Wilkes ruled, so we undertook as best we could to comply with the ruling, but I want it to be clear that we do feel surprised.

There have been other depositions that have been taken in this West Virginia litigation, other expert depositions, where this objection has

Page 304 not been made. This is the first time this 1 2 objection has been raised, and it's -- and there 3 have been depositions taken of other experts who have also testified in other cases. 5 So we -- we did forego lines of inquiry that we thought were important and that we had 6 7 planned to cover today, but we did not. MR. ARBITBLIT: Your position is 8 Let's move on. 9 stated. MR. METZ: Okay. I would suggest --10 11 this is Carl Metz. I'd like to go off the record briefly just for a routine break. I'm happy to 12 13 come back in five minutes or less. I'd also ask if the videographer could give us a current on-record 14 15 tally, so I know where I'm starting from. 16 VIDEO OPERATOR: Sure, currently. 17 Right now, we've been on the record for - double-18 check here - 5 hours and 6 minutes, approximately. 19 MR. METZ: Okay. We can go off the 20 record. 21 VIDEO OPERATOR: Going off the record. 22 The time is 4:48 p.m.(A recess was taken after which the 23 24 proceedings continued as follows:)

VIDEO OPERATOR: Now begins Media Unit 8 in the deposition of Katherine Keyes. We're back on the record. The time is 4:57 p.m.

EXAMINATION

BY MR. METZ:

- Q. Good afternoon, Doctor Keyes. My name is Carl Metz. I represent Cardinal Health. I don't believe we've met before.
 - A. No.
- Q. And I apologize that I appear to be questioning you from deep in some shadows. I have a choice to my office between a place that has good lighting but unreliable Internet or a place that has good Internet but bad lighting, so I made the obvious choice.
- A. These are COVID-era tradeoffs we have to make routinely. So I completely understand.
- Q. I'd like to begin by asking some follow-up questions about two of your earlier answers that I've noted from the realtime. Do you recall testifying about a study by a Doctor Compton, and you were speaking about the availability of additional data subsequent to the time that that study came out. Do you recall that?

A. I do.

Q. Okay. And as reflected in the realtime around page 201, you had an answer that was along the lines of, "There was insufficient data, but I think now any reasonable epidemiologist would conclude that there was more than sufficient evidence."

Do you recall giving that answer?

- A. You know, I can't quite hear you. You're coming in and out a little bit. I wonder if you could get closer. I apologize.
- Q. No problem. Let me see if I can figure out the source of that.
- A. I think I would say my answer is that I -- I understand Compton's -- Compton's, you know, reading of the literature, that it was insufficient at that time.

And there certainly has been more literature on opioid policy since then. It was specific to his statement on opioid policy.

- Q. I see. And can you explain why you used the phrase "reasonable epidemiologist" would --
- THE COURT REPORTER: I'm sorry, I'm having a hard time as well.

- A. Right. Could you repeat the question?
- Q. Well, I can. But I want to figure out the systemic issue first. Why don't we go briefly off the record?

VIDEO OPERATOR: Going off the record.

The time is 5:00 o'clock p.m.

(A discussion was had off the record after which the proceedings continued as follows:)

VIDEO OPERATOR: Now begins Media Unit 9 in the deposition of Katherine Keyes. We're back on the record. The time is 5:02 p.m.

BY MR. METZ:

Q. Doctor Keyes, thank you for bearing with me with the audio issues I was having. Let me read the quote back to you that I was trying to ask you about before, and I saw that you grabbed the Compton study. My question is not going to be about the Compton study; it's going to be about a particular phrase you used in your answer.

You said around -- somewhere around page 201 of the realtime that there was insufficient data, "but I think now any reasonable epidemiologist would conclude that there is more

Page 308 than sufficient data." 1 2 Do you recall giving that answer? 3 Α. T do. Why did you use the phrase "reasonable 5 epidemiologist" in reference to this data issue? I just -- I simply meant that anyone who is 6 7 trained to read this literature, I think, would -would conclude that there is more data at this 8 9 point for which sufficient conclusions can be 10 drawn. 11 And do you consider yourself to be a reasonable epidemiologist? 12 13 Α. T do. And in another of your answers today -14 15 specifically, I think, this was around page 175 of the realtime - and you were testifying in reference 16 17 to your direct and indirect attribution, and in 18 your answer at several -- in several places, you mention the concept of trying to provide 19 20 conservative estimates. 21 Do you recall that? Α. I do. 22 23 And in context of epidemiology, what does 24 it mean to offer a conservative estimate?

A. Specifically, I -- it depends on the context, and certainly it's not across the board that we would want to provide, quote/unquote, conservative estimates. But for the purpose of what I was engaged in in a section of the report - which was this attribution of deaths to prescription opioids, both directly and indirectly - I felt that a conservative approach would be -- would be the most reasonable approach to use for that section.

I do a lot of opioid simulation modeling, and that type of approach is -- is a very well-accepted methodology in my field, where when we -- when there is uncertainty around a certain percentage, then we'll use a conservative indicator so that we don't kind of overestimate a certain parameter.

Q. Okay, thank you. And I believe specifically your answer - at least according to the realtime - was, "I wanted to apply the most reliable methodology based on my field of expertise in opioid simulation and we often try to" - and I think there might be a typo here, it might be - apply, "conservative estimates in these

circumstances."

Does that sound correct to you?

- A. It really depends on what the specific question that we're trying to answer and what the specific parameter that we're trying to estimate is, whether we want a quote/unquote conservative estimate or not, but in many cases, in my experience doing a lot of these similar types of analyses in my field, when there is uncertainty, you know, applying a conservative parameter gives you some assurance that you're not overestimating the -- the harm.
- Q. And to be clear on this point, you regard your own calculation of the deaths that you say are directly and indirectly attributable to prescription opioids, you regard that to be a conservative estimate? Is that correct?
- A. That was specifically with regard to the indirect attribution parameter.
 - Q. So my question --
 - A. -- conservative estimate.
- Q. Okay. So what my question as to the exercise as a whole, do you regard that exercise as a whole what's ultimately reflected in Figure 16

of your errata - do you consider that to be a conservative estimate?

A. I wouldn't -- I wouldn't say across the board that every estimate is conservative. I think for that particular parameter, because there was uncertainty around the percentage, I felt that a conservative estimate was a reliable way to apply my methodology.

But I wouldn't apply that same logic to every parameter that I estimated in that section of the report.

- Q. Okay, I see. So if -- if you thought you had more concrete numbers, for example, you might not feel as constrained to apply a conservative approach; you might just apply whatever you think is the most -- the most accurate based on the numbers you have. Would that be fair?
 - A. That would be one example, yes.
- Q. Is there uncertainty about the OUD population in Cabell County?
 - A. Yes.

Q. And I take it then you would have applied a conservative approach to try and to estimate that uncertain number. Is that fair?

- A. I tried to apply the most reasonable and reliable numbers that I could.
- Q. The most reasonable and reliable numbers that you could apply. Is that your testimony?
- A. That's my testimony. That I felt were reasonable and reliable based on my -- my knowledge of the field.
- Q. Do you consider that OUD estimate to be conservative?
- A. Yes.
- 11 Q. Now, would you turn to page 42 of your 12 report? Which I believe is Exhibit 2.
- 13 A. Yes.

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- Q. Are you there?
- 15 A. Yes.
 - Q. And about, I think, three-quarters of the way down, you have a paragraph where you're -- where you're describing the Larney paper and how you applied the methodology from the Larney paper to -- as part of calculating what you consider to be the OUD population in Cabell County; is that correct?
 - A. That's right.
 - Q. And you describe here at page 42 the need

Page 313 to make an adjustment to a mortality estimate that 1 2 is found in the Larney paper in order to account 3 for the greater lethality of illicit fentanyl. Is that correct? 4 5 Α. That's correct. Okay. And specifically -- well, before I 6 Q. 7 ask that, why does the greater lethality of fentanyl require you to make an adjustment to the 8 9 figure that's in Larney? Because I would estimate that after 2015, 10 the death rate -- the overdose death rate for 11 12 individuals with OUD would be higher than .52 per 100,000. 13 And just to explain the logic of this, am I 14 15 correct, the point is: Since fentanyl is much more lethal, the number of overdose deaths attributed to 16 17 fentanyl implies a smaller population that's 18 encountering fentanyl for --(Inaudible). 19 Α. Okay. And so in the logic of that 20 Ο. 21 approach, the more lethal your estimate of 22 fentanyl, the smaller the OUD population you would 23 -- you would calculate as a result. Correct?

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That's not exactly correct. It's not the

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Α.

-- it's not the direct lethality comparison. It's the total drug overdose death rate that I'm trying to estimate.

So fentanyl -- whatever -- however more lethal fentanyl is than heroin, it wouldn't be a direct multiplier to the death rate, because we're -- what we're trying to estimate is the probability of overdose given OUD, not per use, you know, in a direct comparison of heroin with fentanyl and heroin without fentanyl. That would be --

- Q. Let me ask that question a little bit better. All else being equal, the greater the lethality of fentanyl as compared to the substances that are studied in Larney, the smaller the OUD population you would infer based on the number of overdose deaths that have occurred, correct?
- A. Sorry, that -- can you perhaps where we need to come to consensus is your definition of the word "lethality."
- Q. Sure. I'm using that term in reference to the information contained inside the parentheticals on page 42, specifically where you write, "(the overdose rate due to heroin and synthetic non-methadone opioids increased by a factor of

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Page 315 three from 2011 to 2015)." 1 2 Α. Okay. 3 So with that understanding, if -- well, let me back -- let me back up. You multiplied it by 5 three in the belief that fentanyl is more lethal than heroin, and so the number of deaths that are 6 7 coded as fentanyl contributed to implies a smaller population that is encountering fentanyl relative 8 9 to what would be the same if you had that many deaths attributed to heroin. Right? 10 11 That's right. Α. Okay. And so just keeping that 12 Ο. 13 number three in reference, if your estimate was that fentanyl was six times more lethal, right, it 14 15 would result in -- from this calculation, it would result in a smaller OUD population, correct? 16 17 Α. So again, I -- you're using the term "more 18 lethal," and that's not exactly the method -- it doesn't really -- in order to apply the 19

I guess what you do mean by "six times more lethal?" If the drug overdose rate is six times -- the way I would use it -- the way I would

methodology, at least epidemiologically the way we

use the term "more lethal" --

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use the multiplier of three is my estimate is that the drug overdose rate is now three times higher than it was before fentanyl, which is what I observed in the data.

Q. Okay.

- A. If that number had been six times higher, then I would have used a multiplier of six. But the fact that fentanyl might be six times more lethal is not how you apply that methodology. Does that make sense?
- Q. Yeah, you've now answered it in the way I thought I was asking it.
 - A. Okay. I apologize.
- Q. My terminology wasn't aligning with yours, but now I understand how you've used it. And just to follow through with that last point, if all else remained equal in the table but you'd used the multiplier of six rather than the multiplier of three, the OUD population you would have calculated would have been smaller than the one you in fact calculated; is that right?
 - A. That's correct.
- Q. And if that number was I don't know twelve, it would be smaller still, right?

Page 317 Α. 1 Correct. 2 MR. ARBITBLIT: Objection. 3 Q. Now, you cite here two sources as the basis for that multiplier of three, correct? I do. 5 Α. And those -- those sources are what you 6 Ο. 7 were basing that multiplier on, right? Α. Yes. 8 9 Q. And if you look in your citations list -- I 10 want to ask you first about one of them. 11 At No. 195, that's the Dowell paper, 12 right. 13 That's right. Α. 14 And that paper was published in 2017? Ο. 15 Α. That's right. And the data contained within the paper 16 Ο. only goes through 2015, correct? 17 Do you have it as an exhibit? 18 Α. 19 Q. I do. 20 May I --Α. 21 Ο. Let me -- before I go there, let me first ask this -- in your report, you reference the 22 23 increase in the overdose rate from 2011 through 24 2015, correct?

Page 318 That's right. Α. Ο. And do you believe that's because of any relevant time period in the Dowell paper? Α. -- the paper --Well, let me ask this -- if the Dowell paper had the same statistics through 2018, would you have stopped at 2015? Α. Yeah. MR. ARBITBLIT: Objection. You would have? Q. I would have stopped at 2015. That was the relevant time period I was interested in. The 2011 to 2015 time period. Because that covers the direct pre- and post-fentanyl introduction. And so that small window was the correct window to

If you went through 2018, you would get a much bigger factor, but that wouldn't be relevant to the multiplier that I was interested in.

O. It wouldn't be relevant?

estimate the factor of three.

A. Correct.

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- Q. Did you -- did you consider applying your multiplier based on data through 2018?
 - A. I considered it and rejected it as

Page 319 nonreliable. 1 2 Ο. Okay. Did you -- had there been any 3 changes in the availability of fentanyl since 2015? And by "fentanyl," I mean illicit fentanyl. 5 Have there been any changes in the availability of fentanyl? I'm not quite sure what 6 7 you mean. It's -- sticking with West Virginia, is 8 9 illicit fentanyl today available as readily as it was in 2015? Or more or less? 10 11 MR. ARBITBLIT: Objection. 12 Α. I don't have data to speak to that topic. You didn't look at that? 13 Q. The availability of fentanyl in 2018? 14 Α. 15 Ο. Sorry. I don't know of data that would -- that 16 Α. 17 would tell us how more available fentanyl was in 18 2018 than in 2015. We can -- there's synthetic overdose death rates, but not -- I don't know of 19 any data on the availability of fentanyl. Illicit 20 21 fentanyl. Are there forms of illicit fentanyl 22 23 available today different in any way from the forms 24 of illicit fentanyl that was available in 2015?

- A. Could you give me an example of a form?
- Q. Sure. Fentanyl versus analogs like carfentanil.
 - A. I don't know with respect to West Virginia.
- Q. Did you look at that in connection with attempting your OUD population estimate?
- A. That would not be relevant to my OUD population estimate. So no, I didn't.
- Q. It would -- it -- if a more potent form of fentanyl was available -- a fentanyl analog was available in 2018 that wasn't available in 2015 and that contributed to a higher overdose per 100,000 people -- population, that wouldn't be relevant at all to an attempt at conservatively estimating the OUD population based on overdose deaths?

Is that your testimony?

A. My testimony is that it -- I felt that it was a reliable methodology to use the time period directly pre and directly post the introduction of fentanyl to estimate the total overall increase in the death rate for those years and apply it there forward to all synthetic opioid death rates with the -- with the estimate that the overall drug overdose death rate is approximately three times

Page 321 higher. 1 2 I think that that's a reliable 3 methodology to use. It's a methodology that's commonly used in my field. Is a methodology that's commonly used in 5 your field when you have unstable patterns? 6 7 MR. ARBITBLIT: Objection. Α. That's right. 8 9 It is -- your testimony is it is commonly 10 used even when you have unstable underlying 11 patterns that you're trying to use as the basis for 12 the prediction? The correction is due to the unstable 13 Α. 14 patterns. 15 But I guess my question -- sorry, it would 16 have been a little more clear. If the pattern 17 continues to be unstable after the period in which 18 you used to select your multiplier, is that an accepted methodology within the field of 19 epidemiology to ignore that further changes in the 20 21 pat -- in the -- in the underlying number and just 22 stick with the number you would pick from 20 --23 from a prior year, when there's continued change? 24 MR. ARBITBLIT: Objection.

A. I don't have any evidence of a -- of a continued change.

- Q. Did you investigate whether or not there was evidence of a continued change?
 - A. It did not come up in my literature review.
- Q. Okay. Do the sources you cite on this page reflect a continued change?
- A. I'm sorry, what do you mean by "continued change"?
- Q. I mean, your multiplier is based on the increase in the mortality rate for overdose deaths with synthetic opioids present from 2011 to 2015. Did that number continue to increase from 2015 through 2018?

MR. ARBITBLIT: Objection.

A. I believe that I've explained the methodology. So even if the synthetic opioid overdose at -- I -- even if the synthetic opioid overdose rate continues to increase, the correct multiplier would be the one that's -- that's directly pre and post the introduction of the cause of the change that we're trying to estimate.

It would be incorrect to apply a change from, for example, 2011 to 2018. And that's why I

didn't do that.

- Q. And again, that's because you're assuming there were not any changes in what was causing the increased mortality over that period of time.

 Correct?
 - MR. ARBITBLIT: Objection.
- A. I am assuming that the contribution of synthetic opioids in terms of the percentage increase in drug overdose death was similar after 2015 than pre-- 2013, essentially.
- Q. Have there been any changes since 2015 in the ways in which illicit fentanyl is -- is sold on the streets or the forms in which it appears?
 - A. Can you give an example of that?
- Q. Sure. An example would be -- you testified, I think, earlier fentanyl being available as an adulterant in heroin. Are you aware that there are also prescription -- sorry, excuse me.
- -- that there are counterfeit prescription pills made to resemble a prescription opioid that are often laced with fentanyl and cause death?
 - A. I am aware that there are counterfeit

prescription opioids and that some of them have fentanyl in them.

Q. And are you aware that people have overdosed and died from pills like that?

- A. Yes, I have -- I'm aware that that occurs.
- Q. In forming your conservative estimate of the OUD population in Cabell/Huntington, did you investigate whether or not these types of counterfeit pills were more -- more available after 2015 than they were in 2015?
- A. Again, that -- that wouldn't change my estimate if they were more available versus less available, as long as the pre/post fentanyl introduction multiplier is -- is the accurate multiplier, which is the one that I've used.

So because there are more fentanyl deaths, what matters in terms of the validity of the estimation, is the probability of death per use.

- Q. And is carfentanil more potent than what was generally referred to as synthetic fentanyl when fentanyl first appeared?
- A. I would need to look at -- there are a number of different synthetic opioids. I was

assuming kind of an average of them.

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- Q. Okay. Well, I've already asked whether you know if carfentanil is -- is present and available in 2015. But my question more specifically was:

 Do you know whether or not carfentanil is more potent and therefore considered more dangerous than other synthetic fentanyls?
- A. I would have to look at the range of all synthetic fentanyls. Carfentanil is very potent. But you know, if you want to show me some data on the potency of various synthetic opioids, I can answer your question. But just carfentanil compared to a random synthetic opioid, I don't have -- I can't -- that's not sufficiently specific to answer your question.
- Q. Okay. Can you open -- let me just make sure I have the number correct.

-- Exhibit 86?

KEYES DEPOSITION EXHIBIT NO. 86

("Underlying Factors in Drug Overdose

Deaths" by Dowell, et al. dated

12-19-17 was marked for identification

purposes as Keyes Deposition Exhibit

No. 86.)

- Q. This is the Dowell paper that we were speaking of a moment ago, Exhibit 86?
 - A. Yes.

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- Q. And that's the paper that -- you list it at No. 195 in your reference material; is that correct?
 - A. That's right.
- Q. And if you turn to the fourth page, am I right that the basis for your multiplier is an approximation of the information that's presented at -- in the first draft on page 4 of this paper. Is that right?
- A. That's part of it. I have another citation as well.
 - Q. Your Citation 194, correct?
 - A. Let me -- that's right.
 - Q. Okay. So just so I understand first, so the basis for this multiplier of three is that as you see the calculation of illicit opiate overdose deaths from 2011 through 2015 increased in the neighborhood of two deaths per 100,000 up to around but a little bit above six deaths per 100,000, correct?
 - A. That's right.

- Q. Okay. I take it based on some of your prior answers, you are aware that that metric, deaths per 100,000, increased from 2015 to 2016. Correct?
- A. Again, I'm aware of that. But the correct calculation is the comparison of 2011 to 2015. I mean, the other reference I cite here, the synthetic opioid overdose data, also goes up to 2018. But it would be incorrect to use a multiplier comparing 2018 to 2011. That's why I did not do that.
- Q. That wasn't my question. My question was: You are aware that from 2015 to 2016, it increased, correct?
 - A. Yes.

- Q. And you're also aware that that same metric increased from 2016 to 2017, correct?
 - A. Yes. It increased 2016 to 2017.
- Q. And it further increased from 2017 to 2018, correct?
 - A. For illicit opioid overdose deaths? I would need to check the data to confirm that.
 - Q. Okay. Well, we can find information on that at the web page you've listed on -- as

Page 328 Reference No. 194, correct? 1 2 Α. That information would be on Reference 194. 3 Q. As you sit here, do you recall what that resource says was the West Virginia-specific 5 mortality -- or deaths per 100,000 in 2018? I don't recall sitting here. 6 Α. 7 As you sit here today, do you believe that number to be higher or lower than the six per 8 9 100,000 that's reflected in the Dowell paper? I would need to review the data. 10 11 Ο. Okay. Do you know where within the ranking of states that figure for West Virginia ranks as 12 13 among -- among all states? I don't recall. I'm sorry. 14 15 And is it your testimony that the higher rate of deaths per 100,000 as of 2018, that is not 16 17 in any way the result of differences in the 18 availability and frequency with which fentanyl is present in various drugs of abuse? 19 20 MR. ARBITBLIT: Objection. 21 Α. That's not my testimony. Is your testimony that if there had 22 Ο.

Q. Okay. Is your testimony that if there had been differences and changes in the availability and frequency with which fentanyl is present in

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Page 329 various drugs of abuse, that that wouldn't be relevant to your calculation of OUD population based on the number of deaths occurring? Α. That's also not my testimony. Well, then what is your testimony as to why the higher rate of death per 100,000 as of 2018 -why that is not apparently considered at all in the calculation? Α. So I can --MR. ARBITBLIT: Objection. Asked and answered. THE DEPONENT: Right. Α. I -- my testimony is not -- so you said that my testimony is that had there been any differences or any changes in the availability and frequency with which fentanyl was present, it wouldn't be relevant. That's not what I'm saying.

I'm saying that based on the information that I have, I don't -- I didn't find any changes in or differences in availability or frequency that were relevant. Not that there were no changes that could have been relevant.

I did not find any changes that were relevant to my calculation. Had I found such

Page 330 changes, I would have changed my calculation. 1 2 Ο. Okay. I think what you testified was, you 3 used the multiplier of three ending in 2015 because that was the period immediately before and after 5 the change. Right? Α. That's right. 6 7 Okay. And so my question is: If there were further changes after 2015, wouldn't that mean 8 9 that your multiplier is not capturing the relevant --10 11 Α. No. 12 Q. -- changes? 13 I feel that I've answered this question now Α. a number of times. 14 Well, I --15 Ο. 16 Α. No. 17 -- respect -- I think you may have Q. 18 misunderstood. That's why I clarified the nature of my question. So can you answer that question 19 20 now? 21 MR. ARBITBLIT: Objection, asked and 22 answered multiple times. If you have anything additional to say 23 24 about it, you can.

A. Can you ask your question again?

Q. Sure. You had told me that the reason you stuck with 2015 deaths per 100,000 even though you knew that there were higher estimates for later years and even though you fully understand that using those higher estimates would reduce your OUD population, that the reason for that is you wanted to have a multiplier to capture the period of the year before and after the change.

So my question was: If there were further changes in the availability, the potency, the number of ways in which it appeared, the transparency with which it appeared, if any or all of those things changed subsequent to 2015, would your multiplier really be picking up, as you put it, the change?

MR. ARBITBLIT: Objection, vague, ambiguous, argumentative, compound, asked and answered.

A. No. That's the short answer to your question, is no. The correct calculation would be 2011 to 2015 because the calculation is not capturing -- the purpose of the calculation is not to capture the change from one time to another;

it's to estimate the change in the probability of drug overdose death, given a change in the underlying death rate.

And so the appropriate way to calculate that using the methodology that is reliable in my field would be to use a pre/post comparison in an interrupted time series, which is what I did.

If there are further changes after 2015, it would be biased to include that as part of my interrupted time series.

So the way you are describing the methodology would be incorrect. The way I'm describing the methodology is correct under the reliable methods of my field.

Q. So let me just make sure I understand that. If there were further changes in how dangerous illicit fentanyl was as measured by the number of deaths it caused per 100,000, that would not be relevant to your estimate of the OUD population based upon the number of deaths attributed to fentanyl?

MR. ARBITBLIT: Objection.

A. I don't know how to describe this methodology again. Changes in --

Q. That's not what I asked you to do. I asked you a question. I'd like you to answer my question.

A. Okay.

MR. ARBITBLIT: Asked and answered multiple times. You're badgering at this point.

You want an answer to a question, you've got the answer several times.

- A. Could you rephrase the question?
- Q. Can you --
- A. I don't understand the question.
- Q. If there had been changes subsequent to 2015 in the dangerous nature of illicit fentanyl such that it is more dangerous today than it was in 2015, then for purposes of estimating the OUD population based on the number of deaths attributed to fentanyl, don't you need to take into account those changes subsequent to 2015?

MR. ARBITBLIT: Objection.

A. No.

MR. ARBITBLIT: Asked and answered.

Q. Okay. I want to ask you some questions that relate to your calculation of deaths that you say are directly and indirectly attributable to

Page 334 prescription opioids. And first, I just want to 1 2 understand something -- a few things about the 3 mechanics of this -- this calculation. So you've described in earlier 4 5 testimony, if a prescription opioid was noted at all being present, then for purposes of your 6 7 methodology, you coded that death as either T40.2 or T40.3, depending on which substance was found to 8 be present. Is that fair? 9 10 Α. That's right. And so what about when there were T40.1 and 11 12 T40.4 -- and just for purposes of this, I will --13 I'll confine my questions to after 2013. If both T40.1 and T40.4 were present 14 15 but T40.2 and T40.3 were not present, did you choose one or the other as between T40.1 and T40.4? 16 17 Α. Can you refer me to the section of the 18 report where this is described? 19 Sure. I'm on page 32. Sorry, 33. Q. 20 Α. Page 33? 21 Ο. I am on page 33 where at the top you describe all the various ICD-10 codes and how you 22 23 use them, but I'm also referring to testimony you

gave earlier here today. I'm not suggesting that

- all of this is disclosed in your report. That's partly why I'm asking the question.
- A. Okay. Okay, so your -- so -- let me just go back to your question.
- Q. Let me back you, because I think I may have lost you in my question. We established in your earlier testimony and I think you just reconfirmed for me if a prescription opioid was present at all, then for purposes of the calculation you are doing here for Figure 8 and Figure 16, you classified that by the prescription opioid rather than by other opioids that were present. Correct?
 - A. That's correct.

- Q. Okay. So my question is: If there were multiple substances but not T40.2 and T40.3, it was heroin and fentanyl that were present -- which I think you've testified, that is a circumstance at which people have overdosed and died, from the combination of heroin and fentanyl. Correct?
 - A. That's right.
- Q. Okay. So for those deaths, the death certificate would say, T40.1, heroin and T40.4, fentanyl. And my question is: Did you put those

Page 336 deaths into one column or the other? And if so, 1 2 which one? 3 Α. One column -- which -- which two columns am I considering? As between heroin and fentanyl, T40.1 and 5 T40.4. If both were noted as present but no 6 7 prescription opioid. I see. So for T40.4 -- oh, when they both 8 9 were present, we used a -- I used a correction for 10 fentanyl. Most likely that was in -- that was in 11 the bucket of not prescription opioids, although 12 some portion of fentanyl deaths are due to prescription fentanyl, and so I estimated that 13 based on the available literature. 14 15 Okay. I'm going to -- I'm going to ask you all about that estimation in a minute. I just 16 17 meant in terms of where you were coding the result. 18 Is it correct that if both heroin and fentanyl were present and therefore you had both T40.1 and 19 20 T40.4 --21 Α. Uh-huh. -- did you choose one of those or the other 22 23 in order -- for categorizing those, or did you use 24 -- did you include them under both columns?

- A. Which columns? Is there a specific figure that you're referring to?
- Q. I --

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- A. The direct and indirect attribution?
- Q. I'm referring, in part, to -- let me back this up. You performed -- I think disclosed in your work papers, various calculations that are based upon how you have categorized deaths available through the CDC WONDER data, correct?
- A. Yes.
 - Q. And some of those calculations are dependent upon ratios of who -- of deaths that you put in the T40.2 versus T40.3 versus T40.4, correct?
 - A. No.
 - Q. There's not a calculation that is a ratio of that?
- A. I'm sorry, what's the ratio? Ratio to -no, T40.2 and 3, I included together to estimate
 the rate of prescription opioid overdose.
 - Q. Right. I'm asking you --
- A. The rest of the opioid overdoses were not prescription opioid --
 - Q. You're way ahead of me. I'm asking a more

- foundational question of: In building up the data that is then going to be the product of these calculations, you have deaths that you put into the different categories. Some you coded at T40.1; some you coded at T40.2.
- A. No, these not how it works, because they are not mutually exclusive. You are raising the exact reason why that would not be a reliable methodology.
- Q. I want to make sure I understand you.

 They're not mutually exclusive, because if -- I

 think I missed -- I think your earlier testimony on

 this is different. If prescription opioids were

 present you have T40.2 or T40.3 but also heroin

 is present --
 - A. Right.

- Q. -- does that result in multiple entries, or does that result in a single entry that's in just one column?
- A. I'm -- I'm having a hard time with the column concept. I wonder if you can point me to a figure or a -- in terms of how this resulted in the -- I'm truly just confused. I'm not trying to be obstructionist in any way.

But I don't think that the way you're describing it reflects how I did it.

- Q. Okay. Do you recall producing an Excel workbook as part of your backup material?
 - A. Yes.

- Q. Okay. Do you recall that that workbook has a tab titled "Figure 8" and "Figure 16"?
 - A. Yes.
- Q. And that tab further has various rows and columns of information, right?
 - A. Yes.
- Q. And do you recall that there is a row -- a Column J that is in the descriptive part, it's populated as "T40.2 through T40.4 minus T40.2 and T40.3," which really just means it's T40.4.
 - A. Right.

MR. ARBITBLIT: I'm going to object to the line of questioning without a document that the witness can look at. It's very unfair. If you wanted to question on this, it should be in the box of exhibits.

You're asking her to testify from memory about a document with many tables and figures, and it's just not appropriate.

- Q. Doctor Keyes, did you perform your own calculations in this matter?
 - A. I worked with my research assistant.
- Q. Did you review the calculations that were performed in this matter?
 - A. I did.

- Q. Do you have a working understanding of how the calculations were performed?
- A. No, to be honest with you, I don't. If there's a specific subtraction that -- in a specific column of one specific Excel spreadsheet -- I performed a lot of analyses to come up with these estimates, and I would need to see what specifically you're referring to.
- Q. Well, I'd be happy to provide it, I'm not trying to do it by ambush. I knew that there were a lot of exhibits that had been -- had been sent out. I wasn't aware until today that this Excel spreadsheet was not one of them.

If you'd like, I can e-mail the spreadsheet. But I'm asking you about what was disclosed to us as your -- your backup Excel file, with your calculations, and I just -- I have some questions --

A. I know but you're asking me about specific columns and I'm -- I need something to go off of.

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- Q. Sure. I'd be happy to show you the Excel file, and -- why don't we briefly go off the record. It's something --
- 6 MR. ARBITBLIT: We're not doing that.
 7 You're --
 - MR. METZ: Okay, then I'll continue to ask her questions about her calculations.
 - MR. ARBITBLIT: But did you read the protocol about providing exhibits 48 hours ahead of the deposition? It doesn't say anything about e-mailing them during a deposition. If you find --if you find authority for what you're proposing, then I'd be happy to -- to consider it.
 - But the authority I've seen says you're two days late.
 - MR. METZ: Don, I'm only proposing to do what you've asked for. I'm perfectly content to continue finding out whether this witness knows how these calculation were put together just by asking her working knowledge of them.
 - You and she both requested to see the file I'm looking at. And if you'd like, I can send

Page 342 that to you. If you're going to complain about me 1 2 offering to do that, I won't send it to you and 3 I'll continue asking my questions. MR. ARBITBLIT: You can ask your 4 5 questions, but the witness is within her rights not to be able to not answer them without seeing what 6 7 you're talking about. MR. METZ: Okay, you and I have a 8 9 different view about what experts can be asked 10 about. 11 MR. ARBITBLIT: I didn't say you 12 couldn't ask. 13 BY MR. METZ: Doctor Keyes, do you have a working 14 15 knowledge of the calculations that you produced for 16 your Figure 8, how they were put together? 17 Α. Yes. 18 Does that calculation at any point include a -- the creation of a percentage that is the 19 percentage of deaths coded T40.4 as a share of 20 21 deaths coded T40.2, T40.3 and T40.4 combined. Yes 22 or no. 23 MR. ARBITBLIT: Objection.

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Α.

The Figure 8?

Page 343 Ο. Yes. 1 2 Α. So what we did for Figure 8 was T40.2, 3 T40.3 and a portion of T40.4. Do you know how you arrived at the portion? 4 Ο. 5 Α. Yes, I do. How did you arrive at the portion? 6 Q. 7 We estimated the pre-illicit fentanyl share of prescription opioid overdose deaths that were 8 9 due to T40.4 and applied that share thereafter. Ι 10 attributed those deaths to prescription opioids. 11 Okay. In coming up with that share, are Ο. 12 deaths that are coded T40.4, are they exclusive of -- that same death can't appear as T40.2 or T40.3, 1.3 can it? 14 15 MR. ARBITBLIT: Objection. 16 Α. That's right. 17 Okay. And so getting back to the guestion Ο. 18 I was trying to ask before, you've described the default rule that you would use if T40.2 or T40.3 19 was present, you would code that death as one or 20 21 the other of those. 22 But my question was: If they are not 23 present, you only have T40.1 and you only have 24 T40.4. Did you have a default rule that you

Page 344 applied as to which way that death would be coded 1 2 the one time that it's coded? 3 MR. ARBITBLIT: Objection. T40.4 is not in Figure 8. That's what I'm 4 Α. confused about. 5 Q. Well --6 7 I mean, T40.1 is not in Figure 8. Α. Ο. 8 Right. 9 Α. So if it's coded T40.1 and T40.4, it's 10 coded T40.4, so the same rule that's described in 11 the report was applied. 12 Q. Okay. And you have a Figure 16, correct? 13 Do you want me to go to Figure 16? Α. I'm asking, do you know that you have a 14 Ο. 15 Figure 16? 16 Α. I do know that I have a Figure 16. 17 Ο. Okay. Does the calculation that produces 18 your Figure 16 include T40.1? 19 Yes, Figure 16 does include T40.1. 20 Okay. So just going back to my prior Ο. 21 answer -- my prior question: For purposes of your 22 Figure 16, when you were deciding whether something 23 belonged in the bucket of T40.1 versus T40.4, if 24 both were present - which again, there is a

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circumstance in which there was heroin and fentanyl both present - did you have a default rule that you used in order to decide whether that death would be coded as fentanyl versus coded as heroin?

- A. I would need to look at the spreadsheet to know exactly what mathematical formula that we applied.
- Q. Okay. I don't believe that information is available in the spreadsheet. So my question is simply: As you sit here, you do not know whether a death certificate that was coded as both heroin and fentanyl, whether that for purposes of your analytics was listed as a heroin death or a fentanyl death?
- A. I believe I've been very transparent with my methodology, so if a -- if a death has T40.1 and T40.4, then the share of the T40.4 deaths that were the pre-2013 deaths would be applied to that. That death could only be -- that death could be considered directly or indirectly attributable to prescription opioids based on a proportionate share from the pre-2013 T40.4 deaths.

So it's -- I think the question is a little bit too simplistic of which bucket did T40.1

Page 346 and T40.4 deaths go, because it was based on this 1 2 mathematical calculation. 3 Ο. Is that true, what you just told me, for time periods prior to 2012? 4 5 MR. ARBITBLIT: Objection. Prior to 20 -- prior to 2012, T40.4 deaths 6 7 were considered prescription opioid deaths. Ο. And if it was a T40.1 and a T40.4 both 8 9 present, you would call that a T40.4 death, a fentanyl death, rather than a heroin death. Is 10 11 that fair? MR. ARBITBLIT: Objection. 12 13 Α. I didn't call anything a fentanyl death. Ι attributed that death to prescription opioids. 14 15 Well, but specifically for purposes of your 16 calculation, you attributed it as a T40.4; is that 17 right? 18 MR. ARBITBLIT: Objection. 19 Α. T --20 MR. ARBITBLIT: Vaque. 21 Α. I didn't do that. I didn't attribute anything to T40.4. I attributed things to 22 23 prescription opioids or not prescription opioids. 24 Q. Okay. I'll move on.

Now, you've described for purposes of calculating your Figure 8 that that is the before 2013 share of overdose deaths that was attributable to -- to -- to what you would understand to be prescription fentanyl. Is that a fair summation of what Figure 8 represents?

- A. I considered T40.4 deaths to be prescription opioid deaths prior to 2013.
- Q. Okay. And sorry I wasn't clear. So then for 2013 forward, you've not just been able to take the total that is coded T40.4 because you understand some number of those are illicit fentanyl deaths, they're not prescription fentanyl deaths, right?
 - A. That's right.

- Q. Sorry, I couldn't hear you. Was that a yes?
 - A. Yes, that's right. That's right.
- Q. And so you were starting to describe this calculation that you perform in order to attribute going forward some number of those -- that T40.4 category to -- to prescription opioids, and so my questions are going to relate to that. I want to understand better the logic of the calculation.

A. Sure.

- Q. So when you calc -- first of all, is it correct that in order to come up with the share that you're attributing to prescription fentanyl, your first step is to calculate a ratio of T40.4 deaths as a function of T40.2, T40.3 and T40.4 combined.
 - A. That's right. .
 - Q. And --
- A. Wait, I'm sorry, actually, I don't think that's quite right. I would have to look at the spreadsheet. I'm sorry. I think that we did some manipulation to the -- to account for deaths that had T40.2 and T40.3 as well as T40.4, so I don't think the way you've described it as exactly what we did.
- Q. Okay. If you'll accept -- well, let me just ask it a different way. However you would more precisely phrase that, there is a step in your calculation in which you come up with a percentage that T40.4 represented as a function of some other prescription opioids. You may have made some adjustment to it.

But isn't that correct, that that is

Page 349 one step in your calculation? 1 2 Α. Yes. 3 Q. Is that correct? Α. That's correct. Okay. And if it would help -- I think this 5 Ο. is described in text on page 33 of your report --6 7 Yeah, I was referring to that. Α. -- where you say -- right, "I estimated the 8 9 rate of synthetic opioid deaths from 1999 to 2012, and applied that rate to synthetic opioids over 10 those deaths from 2013 and onwards as a estimate of 11 12 the number of synthetic" "deaths." Correct? 13 Α. That's correct. Okay. So then when you -- and do you 14 recall -- do you recall what that rate was, 15 approximately? 16 17 MR. ARBITBLIT: Objection. 18 Α. Not off the top of my head. 19 Okay. Off the top of your head, do you know whether in calculating that rate you took a 20 21 weighted average of the deaths? I considered doing a year-to-year average, 22 23 but the numbers were unreliable for on a 24 year-to-year basis, and so I summed the total

period from 1999 to 2012 to get a more statistically reliable estimate.

- Q. It's more statistically reliable to sum all the deaths and then take the percentage, correct?

 MR. ARBITBLIT: Objection.
- Q. Maybe I misunderstood. I just wanted to make sure I understood correctly what you said you did to get a more reliable estimate.
- A. Maybe you could be more clear what you mean by a "weighted average."
- Q. Yeah, all I meant was to calculate what you described in your -- the text of your report as a rate, you took -- you formed that rate as a function of all deaths from 1999 through 2012 rather than doing it, as you described, year by year. Is that fair?
 - A. (Nodded affirmatively).
- Q. Okay. And that approach is taking them all together, as opposed to doing it year by year, I think you just testified that's the more reliable way to do that, correct?
- A. I did it both ways, and it didn't make a difference in my final calculation, and I felt that the overall period provided a more reliable

Page 351 estimate. 1 2 Ο. Yeah. Would it surprise you to know that in fact you did the opposite? 3 Α. I'm sorry, I -- I'm not understanding. 4 5 Okay. Now, you then used this rate that Ο. you calculated to estimate going forward the number 6 7 of deaths coded as T40.4 that are -- that continue to be attributable to prescription opioids, in your 8 9 opinion. Is that correct? 10 Α. As an estimate, yes. 11 Ο. Okay. And you do that for the years 2013 12 through 2018; is that right? 13 Α. That's right. And explain to me why -- or how is the rate 14 15 of -- at which prescription opioids -- the rate that that made up of all -- sorry, back this up. 16 17 Explain to me how the percentage share 18 of prescription opioid deaths that was attributable to prescription fentanyl prior to 2012, how that 19 statistic in any way predictive of the share of 20 21 T40.4 deaths, so synthetic only, that were the result of prescription fentanyl. 22 23 Can you explain the logic of that to 24 me?

Sure. Well, to back up, I did the calculations several ways, including estimating post-2013, using the same sort of denominator, if you will, of all prescription opioid deaths that were T40.4 and estimated that as a function of the number that would potentially be attributable to prescription opioids, and then estimated the total number of T40.4 deaths - which is the number of deaths that I was interested - how many of those would be attributable to prescription opioids, and the results were similar no matter how you applied that estimate post-2013, but my interest was in the fentanyl deaths, and so I applied the percentage to the -- to the fentanyl deaths specifically, because those are the deaths that I was interested in identifying an estimate of the number that would be due to prescriptions.

- Q. But how -- given the manner in which you calculated the percentage, how was it informative of the share of T40.4 deaths that are prescription fentanyl versus illicit fentanyl? Is it your testimony that the ratio you calculated is somehow informative of that question? And if so, how?
 - A. So as an example, if prior to 2013 there

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were 100 prescription opioid deaths and two of them were prescription fentanyl deaths, if there were 100 fentanyl deaths after 2013, I would estimate that two of those would be prescription fentanyl deaths.

- Q. And if there were 400 fentanyl deaths, you would -- you would estimate that eight were prescription fentanyl, correct?
 - A. I'm sorry?

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- Q. Under that same logic you just described, if there were 400 prescription fentanyl deaths, you -- your logic would lead you to conclude to eight were the result of prescription deaths.
- A. Using that calculation, that would be the -- that would be the estimate.
- Q. Okay. And if there were -- and if we doubled the number of deaths again, solely within the category of synthetic -- synthetic opioids, you would continue to calculate that that ratio would hold, no matter --
 - A. Yes.
 - Q. -- how many additional deaths there were --
- A. It stays the same.
 - Q. -- a certain percentage will always be the

result of prescription opioids versus illicit -prescription fentanyl versus illicit fentanyl?

A. It's a relatively moot point, because I did it a number of different ways, and the results were robust to the type of correction that you did.

But I applied the correction to the T40.4 deaths overall.

- Q. What sensitivity tests did you perform on this calculation?
- A. As I mentioned, I looked at the T40.4 deaths as a function of overall prescription opioid deaths as well.
- Q. Are you relying on that calculation for the robustness that you just testified to?
- A. I don't -- I guess I don't understand what you mean by that.
- Q. Well, that calculation hasn't been disclosed to us, so my question is: Are you relying on that for purposes of what you just explained was your belief that this is a -- the issue I'm describing -- discussing doesn't matter because you got the same results no matter how you did it so --
 - A. So --

- Q. -- are you relying on that other calculation to support that statement?
- A. In the course of due diligence in epidemiology, we routinely do a range of different sensitivity analyses on the robustness of our results. That's just what we do in the course of our calculations.

So I rely on the estimate that I provided in the report, and I also - because I'm an epidemiologist - I tested the robustness of it using multiple different approaches.

- Q. And did you retain --
- A. So T --

- Q. And did you retain those robustness and sensitivity analyses?
 - A. We were -- I'm sure I did.
- Q. And have they been produced to the defendants in this litigation?
 - A. I was asked to produce the calculations that went into the report. I routinely do sensitivity analyses on my estimates. So no, I have not produced the sensitivity analyses.
 - Q. Okay. Back to my original question: How is the rate at which T40.4 was present among T40.2,

T40.3 and T40.4, how does that rate inform at all the question of how much of T40.4 is then made up of prescription fentanyl versus illicit fentanyl?

How is the one informative of the other?

- A. I would answer it the same way as when you previously asked it: That that is the population that we're interested in estimating this percentage within, and that's routinely done in epidemiology.
- Q. Well, I understand that that's the question you want to answer. But why does that ratio provide you that answer?

MR. ARBITBLIT: Objection, argumentative, asked and answered.

- A. I think I've explained it. It's the T40 -the T40.4 deaths, we wanted the share of those that
 were due to prescription opioids. We knew the
 share of prescription opioid deaths that were due
 to fentanyl in a prior period, and so applied that
 share to the T40.4 deaths, which was the subgroup
 that we were specifically interested in.
- Q. And -- but you understand that after 2013 that the subgroup of prescription fentanyl and illicit fentanyl -- you understand that, correct?

- A. I understand that T40.4 is synthetic opioid death.
- Q. And that after 2013, it's inclusive of illicit fentanyl as well as you assumed some prescription fentanyl. Correct?
- A. I would say synthetic opioids. But yes, it's going to be a mix of illicit and licit.
- Q. And it's your testimony, as a reasonable epidemiologist, that you can look at the population at which prescription fentanyl was present, among other prescription opioids, and that will tell you how much prescription fentanyl was present among prescription fentanyl and illicit fentanyl. That's your testimony?
- A. That's one way to estimate that portion. I did it a number of different ways. None of them made a difference in terms of my opinion or materially to the calculation, and I think it's routine in epidemiology to, for example, apply an estimate of risk to the subgroup at risk to try to get an estimate of the total number.
- Q. Is it routine in epidemiology to have a hypothesis in mind when using statistical analysis, as to how one number might be determinative of some

Page 358 other number? Is that routine? 1 2 MR. ARBITBLIT: Objection. 3 Α. I'm not understanding what the question To have a hypothesis -- what do you mean by 4 "a hypothesis"? 5 Do you ever use the term "hypothesis" in 6 7 connection with statistical analysis? Α. I do. 8 9 O. And what do you use it to mean? 10 I would hypothesize that prescription opioid use causes heroin use, for example. It's 11 12 usually -- a hypothesis is about a cause or a causal connection. 13 And is it important to have a hypothesis 14 when interpreting statistical information? To then 15 base further conclusions on. 16 17 MR. ARBITBLIT: Objection. I wouldn't make a blanket statement like 18 Α. 19 that. 20 Okay. Would you agree or disagree with the statement that "One must infer that a causal 21 relationship exists on the basis of an underlying 22 23 causal theory that explains the relationship 24 between two variables?"

Page 359 MR. ARBITBLIT: Objection. 1 2 Ο. Would you agree with that as a blanket 3 statement? MR. ARBITBLIT: Objection. 4 5 Α. No, I wouldn't agree with that as a blanket statement. 6 And certainly that's not consistent with Ο. the principles you applied in performing this 8 9 calculation, right? 10 MR. ARBITBLIT: Objection. 11 Α. I don't --12 MR. ARBITBLIT: Vaque. 13 It's not consistent or inconsistent. I Α. 14 don't see the relevance. 15 Back to your calculation that you used to 16 produce Figure 8 - and also, then, therefore Figure 17 16 - am I correct that you used West Virginia statewide death totals as the basis for the 18 19 calculation that you performed? 20 For the West Virginia rates, yes. Α. 21 Ο. Well, and am I correct that you then applied that West Virginia rate to -- within Cabell 22 23 and Huntington, but you didn't estimate a separate 24 Cabell and Huntington rate, correct?

- A. For the death rates, we had data on Cabell for a number of years.
- Q. Right. I'm just asking you if you used it for purposes of calculating the rate that you attributed to prescription fentanyl. Is that how you performed the calculation?
- A. Can you just be specific about what rate you mean? Because there's a lot of rates in Figure 8.
- Q. The rates we've been talking about that are discussed at page 33 of your report. It's the rate of prescription fentanyl and the share of other prescription opioids.
 - A. Yes.

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- Q. Do you recall whether you calculated that rate on the basis of West Virginia-specific data or Cabell and -- Cabell County-specific data?
 - A. I would need to look at the spreadsheet.
- Q. Okay. Sticking with the West Virginia piece of it, do you recall approximately how many deaths you attributed to prescription -- to prescription fentanyl in the last year for which you were using actual data, not estimated data? Do you recall approximately how many deaths that was?

A. No.

- Q. Would you believe me if I told you that in the West Virginia portion of your calculation, you -- for 2012, you had 41 deaths?
- A. I really would need to see the -- the spreadsheet.
- Q. That's fine. You can treat this as a hypothetical. I am asking about your calculation, but if you want to treat it as a hypothetical, be my guest. I'd like you to assume that for 2012, you had 41 deaths in that category, and then you begin projecting --
- A. Could you just slow down a minute? Which category? The 20 -- 2012 -- I'm sorry, just go a little bit slowly so I can keep up.
- Q. No problem. 2012, the deaths that had only T40.4 as a contributing opioid. Okay? You with me? The death that you --
- A. So 2012 -- I'm assuming a hypothetical that in 2012, there were 41 deaths with T40.4 --
 - Q. Correct.
- 22 A. -- only. No other T codes.
- Q. Well, you've told us a little bit how you've categorized things. But that's the number

Page 362 represented in -- we'll call it hypothetically. 1 2 But that's in Column J, Row 36 of your calculations, as deaths that had only T40.4 as a 3 contributing opioid, is how you describe it there. 5 I find it very difficult to follow this when I'm not allowed to see the spreadsheet. 6 7 You're more than allowed. I offered to Ο. provide it. Your counsel complained about that 8 9 offer, and so I've not provided it. If you'd like 10 me to provide it, I'd be willing to provide it right now. I suspect Mr. Arbitblit will just 11 complain again. 12 13 So you can have it one way or the other, but you can't have it both ways. 14 15 This is difficult to --16 Ο. That's fine. Why don't I continue my 17 question. I would like for you to assume for 2012, 18 the deaths that you attributed to prescription 19 fentanyl --20 MS. DO AMARAL: I'm sorry, Counsel, 21 can we take a moment? I don't see that Mr. Arbitblit is still on --22 2.3 MR. ARBITBLIT: I'm still on. 24 MS. DO AMARAL: We need to stop the

Page 363 deposition for a minute? Can we take a few 1 2 minutes? 3 MR. ARBITBLIT: No, no, no, no I'm still on. 4 5 MS. DO AMARAL: I'm sorry, Don, I 6 didn't see you: 7 MR. ARBITBLIT: I am still on. Okay, let me ask this again. For the last Ο. 8 9 year for which you had actual data, you had 41 deaths in the category of T40.4 as the contributing 10 opioid, that's the prescription fentanyl. Okay? 11 I had actual data on all years. 12 Α. 13 Well, you don't for 2013 and 20-- I'm using Q. data in contrast to the years for which you 14 15 provided an estimate of the T40.4. Do you understand my meaning now? 16 17 Α. Sure. 18 Okay. For the last year for which you only used actual data, no estimated or projection, there 19 were 41 deaths in that category. Do you recall 20 21 approximately how many deaths your estimate put in 22 that category for the year 2017? 23 MR. ARBITBLIT: Objection. 24 Α. No.

- O. You do not recall?
- A. No.

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Q. If -- I'll ask you just to assume, as a hypothetical - but for the record, this is in Column J, Row 41 - it's 491 deaths. So it's 450 more than in the last year for which you were using data alone rather than a projection.

My question is --

- A. I don't know that that's accurate.
- Q. Well, I -- you can fight me on whether or not it's accurate. I'm staring it at in the face. I'd be happy to show it to you. But if you don't believe me, take it as a hypothetical, and then answer this question:

Do you have a theory that would explain why prescription fentanyl went from killing 41 people in 2012 to killing 491 people five years later? Do you have a theory as to why that would be the case?

- A. Prescription overdose deaths are -overdose deaths are going up overall, so I would
 need to look at the specific underlying data in
 order to answer that question.
 - Q. Do you know whether the availability of

prescription fentanyl specifically increased or decreased over that time period?

- A. It decreased slightly.
- Q. Okay. Do you know whether the potency of prescription fentanyl increased, decreased or stayed the same over that time period?
 - A. I don't know.

- Q. And at least under your calculation, prescription fentanyl specifically was present in ten times as many overdose deaths as a result of your projection and --
- A. Again, I did the projections several different ways.
- Q. And my question is: If it's not because there was more prescription fentanyl available and if it's not because prescription fentanyl was more potent all the sudden, is there a theory that would explain why prescription fentanyl specifically was now causing 12 times as many deaths as before per year?
- A. I am not offering any opinions with respect to that. My only opinion is that the reliability of my estimates was verified as much as I could.

 And so this is the most reasonable and reliable

approach that I could -- that I decided to use.

- Q. And some of those methods that you've just described, validating the reliability of your analysis, you performed additional statistical calculations that lead you to that conclusion, correct?
- A. Yes. Routinely we perform many different statistical calculations when we're estimating trends like this.
- Q. Now, earlier today you made reference to a study that you refer to as the Allen paper? Do you recall that?
 - A. T do.

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- Q. I just want to confirm. Is the title of that paper "Estimating the number of people who inject drugs in a rural county in Appalachia?"
 - A. Is it -- is it one of the exhibits?
- Q. It is not one of the exhibits. Do you recall that title?
 - A. Yeah, I think that that's the title.
- Q. Okay. Do you recall whether one of the co-authors of the paper was a Michael Kilkenny, who's affiliated or employed by the Cabell-

24 | Huntington Health Department?

- A. I don't recall all of the co-authors of the article.
 - Q. Okay. Have you ever spoken to
- 4 Mr. Kilkenny?

3

- 5 A. I don't recall.
- 6 Q. Okay. If you'll just give me one second.
- 7 Could you turn to page 8 of your
- 8 Exhibit B within your report? I have it at -- the
- 9 PDF, the 125th page of your report, if that will
- 10 help. You were testifying about this list earlier.
- 11 A. So -- I don't have those page numbers.
- 12 | Exhibit B, I'm looking for?
- Q. Well, it's your report, but then you have a
- 14 | Materials Considered list which you titled --
- 15 A. Exhibit B, yes.
- Q. Okay. And the eighth numbered page of
- 17 that.
- 18 A. I see. Yes.
- Q. And if you look at Entry No. 134, does that
- 20 refresh your recollection that you spoke with
- 21 | Mr. Kilkenny, Doctor Kilkenny?
- A. I don't remember the conversation, to be
- 23 | honest with you. I talked to a lot of people in
- 24 | that community. So I don't recall the specifics of

the conversation, but maybe I spoke with him.

- Q. Okay. Do you recall raising with Doctor Kilkenny any criticisms of the paper, the Allen paper, that he co-authored?
- A. No.

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- Q. As you sit here today, do you have any criticisms?
- A. Yes, I -- there's a number of limitation to that study.
- Q. Okay. What --
- A. I think it -- it's a study for some things,
 but it's not a -- you know, it's not the end all-be
 all of all studies.
 - Q. What are the most important limitations that you can describe as you sit here today?
 - A. I would need to look at the paper. I can't be -- I can't be asked about one paper of hundreds.
 - Q. Well, you just referenced "a number of limitations." Are there any that stand out in your mind or you simply recall believing it has limitations?
- A. I know that it's a study with limitation.

 If I had a moment to look at the study, I could

 tell you what the most important limitations are,

Page 369 but I don't have it in front of me. 1 2 Okay. Why don't we go off the record. I 3 just want to talk to my colleagues, but I think I may be done. 4 5 VIDEO OPERATOR: Going off the record. 6 The time is 6:20 p.m. 7 (A recess was taken after which the proceedings continued as follows:) 8 9 VIDEO OPERATOR: Now begins Media Unit 10 10 in the deposition of Katherine Keyes. We're back on the record. The time is 6:27 p.m. 11 12 MR. METZ: Doctor Keyes, thank you for your time and your testimony today. I have no 1.3 further questions. 14 15 THE DEPONENT: Thank you. 16 MR. ARBITBLIT: No questions. Are we done? 17 18 MR. METZ: Yeah. 19 MR. HESTER: Yes, I think so. Thank 20 you Doctor Keyes. 21 THE DEPONENT: Thank you very much. 22 VIDEO OPERATOR: If there are no 23 further questions, we're off the record at 24 6:27 p.m., and this concludes today's testimony

Page 370 given by Katherine Keyes. The total number of media units used was ten and will be retained by Veritext. (Having indicated she would like to read her deposition before filing, further this deponent saith not.) --000--

Page 371 STATE OF WEST VIRGINIA, 1 COUNTY OF JACKSON, to wit; 2 3 I, Teresa S. Evans, a Notary Public within 4 and for the County and State aforesaid, duly commissioned and qualified, do hereby certify that 5 the foregoing deposition of KATHERINE KEYES was 6 duly taken by me and before me at the time and place and for the purpose specified in the caption 7 hereof, the said witness having been by me first duly sworn. 8 I do further certify that the said deposition was correctly taken by me in shorthand 9 notes, and that the same were accurately written out in full and reduced to typewriting and that the 10 witness did request to read his transcript. 11 I further certify that I am neither attorney or counsel for, nor related to or employed 12 by, any of the parties to the action in which this deposition is taken, and further that I am not a 13 relative or employee of any attorney or counsel employed by the parties or financially interested 14 in the action and that the attached transcript 15 meets the requirements set forth within article twenty-seven, chapter forty-seven of the West 16 Virginia Code. My commission expires October 25, 2020. 17 Given under my hand this 18th day of September, 2020. 18 19 <%10538,Signature%> Teresa S. Evans 20 RMR, CRR, RPR, WV-CCR 21 22 23 2.4

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7
      Et Al.
      Veritext Reference Number: 4241600
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      Witness: Katherine Keyes Deposition Date: 9/15/2020
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- (e) Review By the Witness; Changes.
- (1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:
- (A) to review the transcript or recording; and
- (B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.
- (2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1,

2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES

OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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